DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 410, 414, 415, 416, 418, 424, 425, 489, and 498

[CMS–1715–P]

RIN 0938–AT72

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1715–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1715–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1715–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for any issues not identified below.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and impacts.

Geri Mondowney, (410) 786–1172, or Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs and geographic practice cost indicies (GPCIs).

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Lindsey Baldwin, (410) 786–1694, or Emily Yoder, (410) 786–1804, for issues related to telehealth services.

Pierre Yong, (410) 786–8896, or Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs (OTPs).

Lindsey Baldwin, (410) 786–1694, for issues related to bundled payments under the PFS for substance use disorders.

Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to the comment solicitation on opportunities for bundled payments under the PFS.

Regina Walker-Wren, (410) 786–9160, for issues related to physician supervision for physician assistant (PA) services and review and verification of medical record documentation.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, Liane Grayson, (410) 786–6583, or Christiane LaBonte, (410) 786–7237, for issues related to care management services.

Kathy Bryant, (410) 786–3448, for issues related to coinsurance for colorectal cancer screening tests.

Pamela West, (410) 786–2302, for issues related to therapy services.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to payment for evaluation and management services.

Kathy Bryant, (410) 786–3448, for issues related to global surgery data collection.

Thomas Kessler, (410) 786–1991, for issues related to ambulance physician certification statement.

Felicia Eggleston, (410) 786–9287, or Amy Gruber, (410) 786–1542, for issues related to the ambulance fee schedule-BBA of 2018 requirements for Medicare ground ambulance services data collection system.

Linda Gousis, (410) 786–8616, for issues related to intensive cardiac rehabilitation.

David Koppel, (303) 844–2883, or Elizabeth LeBreton, (202) 615–3816, for issues related to the Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality Measures.

Katie Mucklow, (410) 786–0537, or Diana Behrendt, (410) 786–6192, for issues related to open payments.

Cheryl Gilbreath, (410) 786–5919, for issues related to home infusion therapy benefit.

Joseph Schultz, (410) 786–2656, for issues related to Medicare enrollment of opioid treatment programs, and enhancements to provider enrollment regulations concerning improper prescribing and patient harm.

Jacqueline Leach, (410) 786–4282, for issues related to Deferring to State Scope of Practice Requirements: Ambulatory Surgical Centers (ASC).

Mary Rossi-Coajou, (410) 786–6051, for issues related to Deferring to State Scope of Practice Requirements: Hospice.

1877AdvisoryOpinion@cms.hhs.gov, for issues related to Advisory Opinions on Application of the Physician Self-referral law.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Megan Hyde, (410) 786–3247, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/PhysicianFee Sched/PFS-Federal-Regulation-Notices.html. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2020 PFS proposed rule, refer to item CMS–1715–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major proposed rule proposes to revise payment polices under the Medicare PFS and make other policy changes, including proposals to implement certain provisions of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment, applicable to services furnished in CY 2020 and thereafter. In addition, this proposed rule includes proposals related to payment policy changes that are addressed in section III. of this proposed rule. We are requesting public comments on all of the proposals being made in this proposed rule.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing to establish RVUs for CY 2020 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and proposals regarding several other Medicare Part B payment policies, Medicare Shared Savings Program quality reporting requirements, Medicaid Promoting Interoperability Program requirements for eligible professionals, the establishment of an ambulance data collection system, updates to the Quality Payment Program, Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations. This proposed rule addresses:

- Practice Expense RVUs (section II.B.)
- Malpractice RVUs (section II.C.)
- Geographic Practice Cost Indices (GPCIs) (section II.D.)
- Potentially Misvalued Services Under the PFS (section II.E.)
- Telehealth Services (section II.F.)
- Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (section II.G.)
- Bundled Payments Under the PFS for Substance Use Disorders (section II.H.)
- Physician Supervision for Physician Assistant (PA) Services (section II.I.)
- Review and Verification of Medical Record Documentation (section II.J.)
- Care Management Services (section II.K.)
- Coinsurance for Colorectal Cancer Screening Tests (section II.L.)
- Therapy Services (section II.M.)
- Valuation of Specific Codes (section II.N.)
- Comment Solicitation on Opportunities for Bundled Payments Under the PFS (section II.O.)
- Payment for Evaluation and Management (E/M) Services (section II.P.)
- Ambulance Coverage Services—Physician Certification Statement (section III.A.)
- Ambulance Fee Schedule—Medicare Ground Ambulance Services Data Collection System (section III.B.)
- Intensive Cardiac Rehabilitation (section III.C.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.D.)
- Medicare Shared Savings Program Quality Measures (section III.E.)
- Open Payments (section III.F.)
- Home Infusion Therapy Benefit (section III.G.)
- Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm (section III.H.)
- Deferring to State Scope of Practice Requirements (section III.I.)
- Advisory Opinions on the Application of the Physician Self-Referral Law (section III.J.)
- Updates to the Quality Payment Program (section III.K.)

2. Summary of Costs and Benefits

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, *see* section VI. of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this major proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was

implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA of 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA of 1997 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA of 1997 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, *see* section II.C. of this proposed rule, Determination of Malpractice Relative Value Units.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VI. of this proposed rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2017 PFS final rule with comment period for a discussion of the last GPCI update (81 FR 80261 through 80270).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work relative value units under the PFS and proposed changes to the practice expense methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of

American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file called ''CY 2020 PFS Proposed Rule PE/HR'' on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2020, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2018. These specialties are Medical Toxicology and Hematopoietic Cell Transplantation and Cellular Therapy. We are proposing to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Medical Toxicology from Emergency Medicine; and
- Hematopoietic Cell Transplantation and Cellular Therapy from Hematology/Oncology.

These updates are reflected in the ''CY 2020 PFS Proposed Rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be

furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file called ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we instead use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

For CY 2020, we are proposing to clarify the expected specialty assignment for a series of cardiothoracic services. Prior to the creation of the expected specialty list for low volume services in CY 2018, we previously finalized through rulemaking a crosswalk to the thoracic surgery specialty for a series of cardiothoracic services that typically had fewer than 100 services reported each year (*see,* for example, the CY 2012 PFS final rule (76 FR 73188–73189)). However, we noted that for many of the affected codes, the expected specialty list for low volume services incorrectly listed a crosswalk to the cardiac surgery specialty instead of the thoracic surgery specialty. We are proposing to update the expected specialty list to accurately reflect the previously finalized crosswalk to thoracic surgery for these services. The affected codes are shown in Table 1.

TABLE 1—PROPOSED UPDATES TO EXPECTED SPECIALTY

CPT code	CY 2019 expected specialty	Updated CY 2020 expected specialty
33414 ..	Cardiac Surgery	Thoracic Surgery.
33468 ..	Cardiac Surgery	Thoracic Surgery.
33470 ..	Cardiac Surgery	Thoracic Surgery.
33471 ..	Cardiac Surgery	Thoracic Surgery.
33476 ..	Cardiac Surgery	Thoracic Surgery.
33478 ..	Cardiac Surgery	Thoracic Surgery.
33502 ..	Cardiac Surgery	Thoracic Surgery.
33503 ..	Cardiac Surgery	Thoracic Surgery.
33504 ..	Cardiac Surgery	Thoracic Surgery.
33505 ..	Cardiac Surgery	Thoracic Surgery.
33506 ..	Cardiac Surgery	Thoracic Surgery.
33507 ..	Cardiac Surgery	Thoracic Surgery.
33600 ..	Cardiac Surgery	Thoracic Surgery.
33602 ..	Cardiac Surgery	Thoracic Surgery.
33606 ..	Cardiac Surgery	Thoracic Surgery.
33608 ..	Cardiac Surgery	Thoracic Surgery.
33610 ..	Cardiac Surgery	Thoracic Surgery.
33611 ..	Cardiac Surgery	Thoracic Surgery.
33612 ..	Cardiac Surgery	Thoracic Surgery.
33615 ..	Cardiac Surgery	Thoracic Surgery.
33617 ..	Cardiac Surgery	Thoracic Surgery.
33619 ..	Cardiac Surgery	Thoracic Surgery.
33620 ..	Cardiac Surgery	Thoracic Surgery.
33621 ..	Cardiac Surgery	Thoracic Surgery.
33622 ..	Cardiac Surgery	Thoracic Surgery.
33645 ..	Cardiac Surgery	Thoracic Surgery.
33647 ..	Cardiac Surgery	Thoracic Surgery.
33660 ..	Cardiac Surgery	Thoracic Surgery.
33665 ..	Cardiac Surgery	Thoracic Surgery.
33670 ..	Cardiac Surgery	Thoracic Surgery.
33675 ..	Cardiac Surgery	Thoracic Surgery.
33676 ..	Cardiac Surgery	Thoracic Surgery.
33677 ..	Cardiac Surgery	Thoracic Surgery.
33684 ..	Cardiac Surgery	Thoracic Surgery.
33688 ..	Cardiac Surgery	Thoracic Surgery.
33690 ..	Cardiac Surgery	Thoracic Surgery.
33692 ..	Cardiac Surgery	Thoracic Surgery.
33694 ..	Cardiac Surgery	Thoracic Surgery.
33697 ..	Cardiac Surgery	Thoracic Surgery.
33702 ..	Cardiac Surgery	Thoracic Surgery.
33710 ..	Cardiac Surgery	Thoracic Surgery.
33720 ..	Cardiac Surgery	Thoracic Surgery.
33722 ..	Cardiac Surgery	Thoracic Surgery.
33724 ..	Cardiac Surgery	Thoracic Surgery.
33726 ..	Cardiac Surgery	Thoracic Surgery.
33730 ..	Cardiac Surgery	Thoracic Surgery.
33732 ..	Cardiac Surgery	Thoracic Surgery.
33735 ..	Cardiac Surgery	Thoracic Surgery.
33736 ..	Cardiac Surgery	Thoracic Surgery.

TABLE 1—PROPOSED UPDATES TO EXPECTED SPECIALTY—Continued

CPT code	CY 2019 expected specialty	Updated CY 2020 expected specialty
33737 ..	Cardiac Surgery	Thoracic Surgery.
33750 ..	Cardiac Surgery	Thoracic Surgery.
33755 ..	Cardiac Surgery	Thoracic Surgery.
33762 ..	Cardiac Surgery	Thoracic Surgery.
33764 ..	Cardiac Surgery	Thoracic Surgery.
33766 ..	Cardiac Surgery	Thoracic Surgery.
33767 ..	Cardiac Surgery	Thoracic Surgery.
33768 ..	Cardiac Surgery	Thoracic Surgery.
33770 ..	Cardiac Surgery	Thoracic Surgery.
33771 ..	Cardiac Surgery	Thoracic Surgery.
33774 ..	Cardiac Surgery	Thoracic Surgery.
33775 ..	Cardiac Surgery	Thoracic Surgery.
33776 ..	Cardiac Surgery	Thoracic Surgery.
33777 ..	Cardiac Surgery	Thoracic Surgery.
33778 ..	Cardiac Surgery	Thoracic Surgery.
33779 ..	Cardiac Surgery	Thoracic Surgery.
33780 ..	Cardiac Surgery	Thoracic Surgery.
33781 ..	Cardiac Surgery	Thoracic Surgery.
33782 ..	Cardiac Surgery	Thoracic Surgery.
33783 ..	Cardiac Surgery	Thoracic Surgery.
33786 ..	Cardiac Surgery	Thoracic Surgery.
33788 ..	Cardiac Surgery	Thoracic Surgery.
33800 ..	Cardiac Surgery	Thoracic Surgery.
33802 ..	Cardiac Surgery	Thoracic Surgery.
33803 ..	Cardiac Surgery	Thoracic Surgery.
33813 ..	Cardiac Surgery	Thoracic Surgery.
33814 ..	Cardiac Surgery	Thoracic Surgery.
33820 ..	Cardiac Surgery	Thoracic Surgery.
33822 ..	Cardiac Surgery	Thoracic Surgery.
33824 ..	Cardiac Surgery	Thoracic Surgery.
33840 ..	Cardiac Surgery	Thoracic Surgery.
33845 ..	Cardiac Surgery	Thoracic Surgery.
33851 ..	Cardiac Surgery	Thoracic Surgery.
33852 ..	Cardiac Surgery	Thoracic Surgery.
33853 ..	Cardiac Surgery	Thoracic Surgery.
33917 ..	Cardiac Surgery	Thoracic Surgery.
33920 ..	Cardiac Surgery	Thoracic Surgery.
33922 ..	Cardiac Surgery	Thoracic Surgery.
33924 ..	Cardiac Surgery	Thoracic Surgery.
33925 ..	Cardiac Surgery	Thoracic Surgery.
33926 ..	Cardiac Surgery	Thoracic Surgery.
35182 ..	Cardiac Surgery	Thoracic Surgery.

We note that the cardiac surgery and thoracic surgery specialties are similar to one another, sharing the same PE/HR data for PE valuation and nearly identical MP risk factors for MP valuation. As a result, we do not anticipate this proposal having a discernible effect on the valuation of the codes listed above. For additional discussion on this issue, we refer readers to section II.C of this proposed rule, Malpractice. The complete list of expected specialty assignments for individual low volume services, including the assignments for the codes identified in Table 1, is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file called ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (*Note:* For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable

adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

• *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 2.

TABLE 2—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, *e.g.,* private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (*e.g.,* drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
A8	Grocery store.
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007).
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.
B4	Rehabilitation Agency.
B5	Ocularist.
C1	Centralized Flu.
C2	Indirect Payment Procedure.
C5	Dentistry.

• *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*), is associated with the global service, CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*).

• *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 3 details the manner in which the modifiers are applied.

TABLE 3—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant.	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

• *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate) − life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally 150,000 minutes.

usage = variable, *see* discussion below in this proposed rule.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, *see* discussion below in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Stakeholders have often suggested that particular equipment items are used less frequently than 50 percent of the time in the typical setting and that CMS should reduce the equipment utilization rate based on these recommendations. We appreciate and share stakeholders' interest in using the most accurate assumption regarding the equipment utilization rate for particular equipment items. However, we believe that absent robust, objective, auditable data regarding the use of particular items, the 50 percent assumption is the most appropriate within the relative value system. We welcome the submission of data that would support an alternative rate.

Maintenance: This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We do not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we do not believe that we have sufficient information at present to propose a variable maintenance factor for equipment cost per minute pricing. We continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

Interest Rate: In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (*see* 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). We are not proposing any changes to these interest rates for CY 2020. The Interest rates are listed in Table 4.

TABLE 4—SBA MAXIMUM INTEREST RATES

Price	Useful life years	Interest rate (%)
<$25K	<7	7.50
$25K to $50K	<7	6.50
>$50K	<7	5.50
<$25K	7+	8.00
$25K to $50K	7+	7.00
>$50K	7+	6.00

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2020 direct PE input public use files, which are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640–67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and postservice periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS.'' Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values.

We also finalized standard times for clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902) at 4 minutes for ''Accession specimen/prepare for examination'', 0.5 minutes for ''Assemble and deliver slides with paperwork to pathologists'', 0.5 minutes for ''Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation'', 1 minute for ''Clean room/equipment following procedure'', 1 minute for ''Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste'', and 1 minute for ''Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).'' We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (''Review patient clinical extant information and questionnaire'') in the preservice period, and CA014 (''Confirm order, protocol exam'') in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463–59464).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2020, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 PFS proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have

been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated prices for the equipment items related to scopes utilized by these services. We did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals in the CY 2018 PFS proposed rule (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 PFS proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channeled flexible video scopes. Our goal was to create an administratively simple scheme that would be easier to maintain and help to reduce administrative burden. In 2018, the RUC convened a Scope Equipment Reorganization Workgroup to incorporate feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we delayed proposals for any further changes to scope equipment until CY 2020 in order to incorporate the feedback from the aforementioned workgroup.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of $1,915), the updated total price of the scope video system would be set at $36,306.

We did not finalize this updated pricing to the scope video system in CY 2018, but we did propose and finalize the updated pricing for CY 2019 to $36,306 along with changing the name of the ES031 equipment item to ''scope video system (monitor, processor, digital capture, cart, printer, LED light)'' to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2020

The Scope Equipment Reorganization Workgroup organized by the RUC submitted detailed recommendations to CMS for consideration in the CY 2020 rule cycle, describing 23 different types of scope equipment, the HCPCS codes associated with each scope type, and a series of invoices for scope pricing. We

appreciate the information provided by the workgroup and continue to welcome additional comments and feedback from stakeholders. Based on the recommendations from the workgroup, we are proposing to establish 23 new scope equipment codes (*see* Table 5).

TABLE 5—CY 2020 PROPOSED NEW SCOPE EQUIPMENT CODES

CMS code	Proposed scope equipment description	Proposed price	Number of invoices
ES070	rigid scope, cystoscopy		0
ES071	rigid scope, hysteroscopy		0
ES072	rigid scope, otoscopy		0
ES073	rigid scope, nasal/sinus endoscopy		0
ES074	rigid scope, proctosigmoidoscopy		0
ES075	rigid scope, laryngoscopy	$3,966.08	5
ES076	rigid scope, colposcopy	14,500.00	1
ES077	non-channeled flexible digital scope, hysteroscopy		0
ES078	non-channeled flexible digital scope, nasopharyngoscopy		0
ES079	non-channeled flexible digital scope, bronchoscopy		0
ES080	non-channeled flexible digital scope, laryngoscopy	21,485.51	7
ES081	channeled flexible digital scope, cystoscopy		0
ES082	channeled flexible digital scope, hysteroscopy		0
ES083	channeled flexible digital scope, bronchoscopy		0
ES084	channeled flexible digital scope, laryngoscopy	18,694.39	5
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	17,360.00	1
ES086	multi-channeled flexible digital scope, colonoscopy	38,058.81	6
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		0
ES088	multi-channeled flexible digital scope, esophagoscopy	34,585.35	5
ES089	multi-channeled flexible digital scope, ileoscopy		0
ES090	multi-channeled flexible digital scope, pouchoscopy		0
ES091	ultrasound digital scope, endoscopic ultrasound		0
ES092	non-video flexible scope, laryngoscopy	5,078.04	4

We note that we did not receive invoices for many of the new scope equipment items. There also was some inconsistency in the workgroup recommendations regarding the non-channeled flexible digital scope, laryngoscopy (ES080) equipment item and the non-video flexible scope, laryngoscopy (ES092) equipment item. These scopes were listed as a single equipment item in some of the workgroup materials and listed as separate equipment items in other materials. We are proposing to establish them as separate equipment items based on the submitted invoices, which demonstrated that these were two different types of scopes with distinct price points of approximately $17,000 and $5,000 respectively.

We noted a similar issue with the submitted invoices for the rigid scope, laryngoscopy (ES075) equipment item. Among the eight total invoices, five of them were clustered around a price point of approximately $4,000 while the other three invoices had prices of roughly $15,000 apiece. The invoices indicated that these prices came from two distinct types of equipment, and as a result we are proposing to consider these items separately. We are proposing to use the initial five invoices to establish a proposed price of $3,966.08 for the rigid scope, laryngoscopy (ES075) equipment item. We note that this is a close match for the current price of $3,178.08 used by the endoscope, rigid, laryngoscopy (ES010) equipment, which is the closest equivalent scope equipment. The other three invoices appear to describe a type of stroboscopy system rather than a scope, and they have an average price of $14,737. This is a reasonably close match for the price of our current stroboscoby system (ES065) equipment, which has a CY 2020 price of $17,950.28 as it transitions to a final CY 2022 destination price of $16,843.87 (*see* the 4-year pricing transition of the market-based supply and equipment pricing update discussed later in this section for more information). We believe that these invoices reinforce the value established by the market-based pricing update for the stroboscoby system carried out last year, and we are not proposing to update the price of the ES065 equipment at this time. However, we are open to feedback from stakeholders if they believe it would be more accurate to assign a price of $14,737 to the stroboscoby system based on these invoice submissions, as opposed to maintaining the current pricing transition to a CY 2022 price of $16,843.87.

For the eight new scope equipment items where we have submitted invoices for pricing, we are proposing to replace the existing scopes with the new scope equipment. We received recommendations from the RUC's scope workgroup regarding which HCPCS codes make use of the new scope equipment items, and we are proposing to make this scope replacement for approximately 100 HCPCS codes in total (*see* Table 6).

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TABLE 6: Proposed Scope Equipment Replacement

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
31505	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31510	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31511	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31512	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31515	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31525	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
31570	ES010	endoscope, rigid, laryngoscopy	$3,178.08	ES075	rigid scope, laryngoscopy	$3,966.08
56820	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
56821	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57420	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57421	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57452	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57454	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57455	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57456	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57460	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
57461	ES004	colposcope	$9,692.02	ES076	rigid scope, colposcopy	$14,500.00
31551	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31552	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31553	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31554	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31574	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31575	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31579	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31580	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31584	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31587	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31591	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
31592	ES063	rhinolaryngoscope, flexible, video, non-channeled	$9,629.93	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92612*	ES027	video system, FEES (scope, camera, light source, image capture, monitor, printer, cart)	$21,675.00	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92614*	ES028	video system, FEESST (scope, sensory stimulator, camera, light source, image capture, monitor, printer, cart)	$25,420.25	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
92616*	ES028	video system, FEESST (scope, sensory stimulator, camera,	$25,420.25	ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
		light source, image capture, monitor, printer, cart)				
31572	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31573	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31576	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31577	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
31578	ES064	rhinolaryngoscope, flexible, video, channeled	$9,000.00	ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
45330	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45331	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45332	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45333	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45334	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45335	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45338	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45340	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45346	ES043	Video Sigmoidoscope	$19,308.56	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
G0104	ES021	fiberscope, flexible, sigmoidoscopy	$10,976.97	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
45378	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45379	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45380	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45381	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45382	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45384	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible	$38,058.81

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
					digital scope, colonoscopy	
45385	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45386	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45388	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
45398	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
G0105	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
G0121	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44388	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44389	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44390	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44391	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44392	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44394	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44401	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44404	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
44405	ES033	videoscope, colonoscopy	$30,561.67	ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
43197	ES026	video add-on camera system w-monitor (endoscopy)	$9,514.13	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43198	ES026	video add-on camera system w-monitor (endoscopy)	$9,514.13	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43200	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43201	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43202	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43206	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43213	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43215	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible	$34,585.35

HCPCS	Current CMS	Description	Price	New CMS	New Description	New Price
					digital scope, esophagoscopy	
43216	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43217	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43220	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43226	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43227	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
43229	ES034	videoscope, gastroscopy	$27,582.01	ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
31590	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31300	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31360	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31365	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31367	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31368	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31370	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31375	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31380	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31382	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31390	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31395	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31400	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04
31420	ES020	fiberscope, flexible, rhinolaryngoscopy	$5,572.07	ES092	non-video flexible scope, laryngoscopy	$5,078.04

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In all but three cases, we are proposing for the new scope equipment item to replace the existing scope with the identical amount of equipment time. For CPT codes 92612 (*Flexible endoscopic evaluation of swallowing by cine or video recording*), 92614 (*Flexible endoscopic evaluation, laryngeal sensory testing by cine or video recording*), and 92616 (*Flexible endoscopic evaluation of swallowing and laryngeal sensory testing by cine or video recording*), the current scopes in use are the FEES video system (ES027) and the FEESST video system (ES028). Since we are proposing the use of a non-channeled flexible digital scope that requires a corresponding scope video system, we are adding the ES080 equipment at the same equipment time

to these three procedures rather than replacing the ES027 and ES028 equipment. In all other cases, we are proposing to replace the current scope equipment listed in Table 6 with the new scope equipment, while maintaining the same amount of equipment time.

We identified inconsistencies with the workgroup recommendations for a small number of HCPCS codes. CPT code 45350 (*Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids)*) was recommended to include a multi-channeled flexible digital scope, flexible sigmoidoscopy (ES085), however, we noted that this CPT code does not include any scopes among its current direct PE inputs. CPT code 31595 was recommended to include a non-channeled flexible digital scope, laryngoscopy (ES080) but it no longer exists as a CPT code after having been deleted for CY 2019. CPT code 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/ biopsy(s)*) was recommended to include a multi-channeled flexible digital scope, esophagoscopy (ES088), but it does not include a scope amongst its direct PE inputs any longer following clarification from the same workgroup recommendations that CPT code 43232 is never performed in the nonfacility setting. In all three of these cases, we are not proposing to add one of the new scope equipment items to these procedures.

We did not receive pricing information along with the workgroup recommendations for the other 15 new scope equipment items. For CY 2020, we are proposing to establish new equipment codes for these scopes as detailed in Table 5. However, due to a lack of pricing information, we are not proposing to replace existing scope equipment with the new equipment items as we did for the other eight new scope equipment items for CY 2020. We welcome additional feedback from stakeholders regarding the pricing of these scope equipment items, especially the submission of detailed invoices with pricing data. We are proposing to transition the scopes for which we do have pricing information over to the new equipment items for CY 2020, and we look forward to engaging with stakeholders to assist in pricing and then transitioning the remaining scopes in future rulemaking.

c. Technical Corrections to Direct PE Input Database and Supporting Files

Subsequent to the publication of the CY 2019 PFS final rule, stakeholders alerted us to several clerical inconsistencies in the direct PE database. We are proposing to correct these inconsistencies as described below and reflected in the CY 2020 proposed direct PE input database displayed on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

For CY 2020, we are proposing to address the following inconsistencies:

- The RUC's Scope Equipment Reorganization Workgroup recommended deletion of the non-facility inputs for CPT codes 43231 (*Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination*) and 43232 (*Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/ biopsy(s)*). The gastroenterology specialty societies stated that these services are never performed in the non-facility setting. After our own review of these services, we agree with the workgroup's recommendation, and we are proposing to remove the non-facility direct PE inputs for these two CPT codes.

- In rulemaking for CY 2018, we reviewed a series of CPT codes describing nasal sinus endoscopy surgeries. At that time, we sought comments on whether the broader family of nasal sinus endoscopy surgery services should be subject to the special rules for multiple endoscopic procedures instead of the standard multiple procedure payment reduction. We received very few comments in response to our solicitation. In the CY 2018 PFS final rule (82 FR 53043), we indicated that we would continue to explore this option for future rulemaking. We are proposing to apply the special rule for multiple endoscopic procedures to this family of codes beginning in CY 2020. This proposal would treat this group of CPT codes consistently with other similar endoscopic procedures when codes within the CPT code family are billed together with another endoscopy service in the same family. Similar to other similar endoscopic procedure code families, we are proposing that CPT code 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*) would be the base procedure for the remainder of nasal sinus endoscopies. The codes affected by this proposal are as follows (*see* Table 7).

TABLE 7—PROPOSED NASAL SINUS ENDOSCOPY CODES SUBJECT TO SPECIAL RULES FOR MULTIPLE ENDOSCOPIC PROCEDURES

CPT code	Short descriptor
31231	Nasal endoscopy dx.
31233	Nasal/sinus endoscopy dx.
31235	Nasal/sinus endoscopy dx.
31237	Nasal/sinus endoscopy surg.
31238	Nasal/sinus endoscopy surg.
31239	Nasal/sinus endoscopy surg.
31240	Nasal/sinus endoscopy surg.
31241	Nsl/sins ndsc w/artery lig.
31253	Nsl/sins ndsc total.
31254	Nsl/sins ndsc w/prtl ethmdct.
31255	Nsl/sins ndsc w/tot ethmdct.
31256	Exploration maxillary sinus.
31257	Nsl/sins ndsc tot w/sphendt.
31259	Nsl/sins ndsc sphn tiss rmvl.
31267	Endoscopy maxillary sinus.
31276	Nsl/sins ndsc frnt tiss rmvl.
31287	Nasal/sinus endoscopy surg.
31288	Nasal/sinus endoscopy surg.
31290	Nasal/sinus endoscopy surg.
31291	Nasal/sinus endoscopy surg.
31292	Nasal/sinus endoscopy surg.
31293	Nasal/sinus endoscopy surg.
31294	Nasal/sinus endoscopy surg.
31295	Sinus endo w/balloon dil.
31296	Sinus endo w/balloon dil.
31297	Sinus endo w/balloon dil.
31298	Nsl/sins ndsc w/sins dilat.

Special rules for multiple endoscopic procedures would apply if any of the procedures listed in Table 7 are billed together for the same patient on the same day. We apply the multiple endoscopy payment rules to a code family before ranking the family with other procedures performed on the same day (for example, if multiple endoscopies in the same family are reported on the same day as endoscopies in another family, or on the same day as a non-endoscopic procedure). If an endoscopic procedure is reported together with its base procedure, we do not pay separately for the base procedure. Payment for the base procedure is included in the payment for the other endoscopy. For additional information about the payment adjustment under the special rule for multiple endoscopic services, we refer readers to the CY 1992 PFS final rule where this policy was established (56 FR 59515) and to Pub. 100–04, Medicare Claims Processing Manual, Chapter 23 (available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf*).

d. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public

requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2020, we are proposing the following price updates for existing direct PE inputs.

We are proposing to update the price of one supply and one equipment item in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we are proposing that the new pricing take effect for CY 2020 for these items instead of being phased in over 4 years. For the details of these proposed price updates, please refer to Table 22, Proposed CY 2020 Invoices Received for Existing Direct PE Inputs in section II.N., Proposed Valuation of Specific Codes, of this proposed rule.

We are also proposing to update the name of the EP001 equipment item from ''DNA/digital image analyzer (ACIS)'' to ''DNA/Digital Image Analyzer'' due to clarification from stakeholders regarding the typical use of this equipment.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if CMS were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-

up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8.

TABLE 8—EXAMPLE OF DIRECT PE PRICING TRANSITION

Current Price	$100	
Final Price	200	
Year 1 (CY 2019) Price	125	¼ difference between $100 and $200.
Year 2 (CY 2020) Price	150	⅓ difference between $125 and $200.
Year 3 (CY 2021) Price	175	½ difference between $150 and $200.
Final (CY 2022) Price	200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer time frame will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475–59480). In each instance in which a commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479–59480).

After consideration of the public comments, we finalized our proposals associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment

accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2020, we received invoice submissions for approximately 30 supply and equipment codes from stakeholders as part of the second year of the market-based supply and equipment pricing update. These invoices were reviewed by the StrategyGen contractor and the submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. The contractor reviewed the invoices, as well as prior data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this research, we are proposing to update the prices of the following supply and equipment items:

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TABLE 9: Proposed CY 2020 Market-Based Supply and Equipment Pricing Updates

CMS CODE	Description	CMS 2019 Price	Prior CMS 2022 Price	Prior CMS 2020 Price	Updated CMS 2022 Price	Updated CMS 2020 Price
SA047	pack, EM visit	$4.176	$7.750	$5.367	$5.468	$4.606
SA099	Kit, probe, cryoablation, prostate (Galil-Endocare)	$3,909.890	$1,539.560	$3,119.780	$4,000.000	$3,939.927
SA106	kit, sinus surgery, balloon (maxillary, frontal, or sphenoid)	$2,543.478	$2,374.330	$2,487.095	$2,338.000	$2,474.985
SD005	biopsy sponge (Histo-Prep)	$0.048	$0.030	$0.042	$0.267	$0.121
SF030	laser tip, diffuser fiber	$699.375	$247.500	$548.750	$730.000	$709.583
SH056	phenylephrine 2.5% ophth (Mydfrin)	$0.391	$0.391	$0.391	$5.465	$2.082
SH058	proparacaine 0.5% ophth (Ophthaine, Alcaine)	$0.615	$0.670	$0.633	$2.353	$1.194
SH084	Kenalog 40 inj	$1.963	$2.360	$2.095	$10.578	$4.834
SJ041	povidone soln (Betadine)	$0.016	$0.040	$0.024	$0.380	$0.137
SL012	antibody IgA FITC	$38.391	$30.025	$35.603	$87.500	$54.761
SL058	embedding cassette	$0.149	$0.120	$0.140	$0.181	$0.160
SL182	mounting media (DAPI II counterstain)	$63.750	$54.000	$60.500	$95.280	$74.260
SL184	slide, negative control, Her-2	$29.400	$29.400	$29.400	$27.500	$28.767
SL195	kit, FISH paraffin pretreatment	$20.850	$20.850	$20.850	$22.000	$21.233
SL196	kit, HER-2/neu DNA Probe	$98.513	$79.050	$92.025	$119.740	$105.588
SL484	Bluing reagent (Ventana 760-2037)	$3.504	$0.450	$2.486	$4.247	$3.751
SL497	(EBER) DNA Probe Cocktail	$8.475	$8.189	$8.379	$10.810	$9.253
EL015	room, ultrasound, general	$369,945.000	$369,945.000	$369,945.000	$410,303.322	$383,397.774
EL016	room, ultrasound, vascular	$466,492.000	$466,492.000	$466,492.000	$479,753.320	$470,912.440
EP001	DNA/digital image analyzer	$193,749.959	$28,160.937	$138,553.619	$225,143.420	$204,214.446
EP007	centrifuge (with rotor)	$4,442.759	$4,896.085	$4,593.868	$4,896.085	$4,593.868
EP015	grossing station w-heavy duty disposal	$21,200.775	$24,276.600	$22,226.050	$25,734.940	$22,712.163
EP017	hood, fume	$4,769.200	$4,741.420	$4,759.940	$5,978.210	$5,172.203
EP024	microscope, compound	$10,066.336	$5,401.295	$8,511.323	$9,764.720	$9,965.798
EP026	microscope, electron, transmission (TEM)	$350,736.063	$445,074.250	$382,182.125	$486,912.125	$396,128.083
EP031	paraffin dispenser (five-gallon)	$2,222.500	$2,222.500	$2,222.500	$2,500.000	$2,315.000
EP033	slide coverslipper, robotic	$30,143.000	$30,143.000	$30,143.000	$52,970.000	$37,752.000
EP036	slide stainer, automated, high-volume throughput	$19,334.532	$35,081.087	$24,583.384	$37,012.544	$25,227.202
EP039	tissue embedding center	$9,612.753	$11,161.000	$10,128.835	$12,560.500	$10,595.335
EP043	water bath, general purpose (lab)	$757.256	$849.673	$788.062	$950.337	$821.616
EP054	water bath, FISH procedures (lab)	$1,977.253	$1,576.010	$1,843.505	$1,576.100	$1,843.535
EP088	ThermoBrite	$5,788.750	$4,795.000	$5,457.500	$4,625.073	$5,400.858
EP089	Camera (Olympus DP21)	$7,719.300	$7,719.300	$7,719.300	$8,715.000	$8,051.200
EP111	Automated Casette Labeler	$9,541.385	$26,579.539	$15,220.770	$26,700.265	$15,261.011
ER041	microtome	$14,087.605	$16,243.420	$14,806.210	$17,709.840	$15,295.017
ER043	microtome, ultra	$33,628.850	$31,378.400	$32,878.700	$35,015.480	$34,091.060

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For most supply and equipment items, there was an alignment between the research carried out by the StrategyGen contractor and the submitted invoice. The updated CY 2020 pricing was calculated using an average between the previous market research and the newly submitted invoices in these cases. In some cases the submitted invoices were not representative of market prices, such as for the centrifuge with rotor (EP007) equipment item where the invoice price of $8,563 appeared to be an outlier. We did not use the invoices to calculate our pricing recommendation in these situations and instead continued to rely on our prior pricing data. In other instances, such as for the kit, probe, cryoablation, prostate (Galil-Endocare)

(SA099) supply item, our research indicated that the submitted invoice price was more representative of the commercial price than our CY 2019 research and pricing. We are proposing the new invoice prices for these supply and equipment items due to our belief in their greater accuracy.

For some of the remaining supply and equipment items, such as the five-gallon paraffin (EP031) equipment and the Olympus DP21 camera (EP089) equipment, we maintained the extant pricing for CY 2019 due to a lack of sufficient data to update the pricing. In these situations where we did not have an updated price for CY 2019, we believe that the newly submitted invoices are more representative of the current commercial prices that are being paid on the market. We are again proposing the new invoice prices for these supply and equipment items due to our belief in their greater accuracy.

In addition, we were alerted by stakeholders that the price of the EM visit pack (SA047) supply did not match the sum of the component prices of the supplies included in the pack. After reviewing the prices of the individual component supplies, we agree with the stakeholders that there was a discrepancy in the previous pricing of this supply pack. We are proposing to update the price of the EM visit pack to $5.47 to match the sum of the prices of the component supplies, and proposing to continue to transition towards this price over the remaining years of the phase-in period.

We finalized a policy last year to phase in the new supply and equipment pricing over 4 years so that supply and equipment values transition smoothly from their current prices to the final updated prices in CY 2022. We finalized our proposal to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price was implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8. For CY 2020, one third of the difference between the CY 2019 price and the final price will be implemented as per the previously finalized policy.

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

(2) Invoice Submission

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. For CY 2020, we noted that some stakeholders have submitted invoices for new, revised, or potentially misvalued codes after the February 10th deadline established for code valuation recommendations. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we would consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices.

(3) Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition. For CY 2020, we are proposing to continue with the third year of the transition of this adjustment to the standard process for allocating indirect PE.

C. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: Work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a comprehensive discussion of the third review and update of MP RVUs, *see* the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596). In the CY 2018 proposed rule (82 FR 33965 through 33970), we proposed to update the specialty-level risk factors used in the calculation of MP RVUs, prior to the next required 5 year update (CY 2020), using the updated MP premium data that were used in the eighth Geographic Practice Cost Index (GPCI) update for CY 2017; however the proposal was ultimately not finalized for CY 2018.

We consider the following factors when we determine MP RVUs for individual PFS services: (1) Specialty-level risk factors derived from data on specialty-specific MP premiums incurred by practitioners; (2) service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and (3) an intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor portion of the direct PE RVU. Prior to CY 2016, MP RVUs were only updated once every 5 years, except in the case of new and revised codes.

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next 5-year review of MP RVUs were determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjusted (or scaled) the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work RVU (or, if greater, the difference in the

clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code was 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach, the same risk factor was applied for the new/revised code and source code, but the work RVU for the new/revised code was used to adjust the MP RVUs for risk.

In the CY 2016 PFS final rule with comment period (80 FR 70906 through 70910), we finalized a policy to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services (using Medicare claims data), and to adjust MP RVUs for risk for intensity and complexity (using the work RVU or clinical labor RVU). We also finalized a policy to modify the specialty mix assignment methodology (for both MP and PE RVU calculations) to use an average of the three most recent years of data instead of a single year of data. Under this approach, for new and revised codes, we generally assign a specialty-level risk factor to individual codes based on the same utilization assumptions we make regarding specialty mix we use for calculating PE RVUs and for PFS budget neutrality. We continue to use the work RVU or clinical labor RVU to adjust the MP RVU for each code for intensity and complexity. In finalizing this policy, we stated that the specialty-level risk factors would continue to be updated through notice and comment rulemaking every 5 years using updated premium data, but would remain unchanged between the 5-year reviews.

Section 1848(e)(1)(C) of the Act requires us to review, and if necessary, adjust the GPCIs at least every 3 years. For CY 2020, we are conducting the statutorily required 3-year review of the GPCIs, which coincides with the statutorily required 5-year review of the MP RVUs. We note that the MP premium data used to update the MP GPCIs are the same data used to determine the specialty-level risk factors, which are used in the calculation of MP RVUs. Going forward, we believe it would be logical and efficient to align the update of MP premium data used to determine the MP RVUs with the update of the MP GPCI. Therefore, we are proposing to align the update of MP premium data with the update to the MP GPCIs, that is, we are proposing to review, and if necessary update the MP RVUs at least every 3 years, similar to our review and update of the GPCIs. If we align the two updates, we would conduct the next statutorily-mandated review and update of both the GPCI and MP RVU for implementation in CY 2023. We are proposing to implement the fourth comprehensive review and update of MP RVUs for CY 2020 and are seeking comment on these proposals.

2. Methodology for the Proposed Revision of Resource-Based Malpractice RVUs

a. General Discussion

We calculated the proposed MP RVUs using updated malpractice premium data obtained from state insurance rate filings. The methodology used in calculating the proposed CY 2020 review and update of resource-based MP RVUs largely parallels the process used in the CY 2015 update; however, we are proposing to incorporate several methodological refinements, which are described below in this proposed rule. The MP RVU calculation requires us to obtain information on specialty-specific MP premiums that are linked to specific services, and using this information, we derive relative risk factors for the various specialties that furnish a particular service. Because MP premiums vary by state and specialty, the MP premium information must be weighted geographically and by specialty. We calculated the proposed MP RVUs using four data sources: Malpractice premium data presumed to be in effect as of December 31, 2017; CY 2018 Medicare payment and utilization data; higher of the CY 2020 proposed work RVUs or the clinical labor portion of the direct PE RVUs; and CY 2019 GPCIs. We will use the higher of the CY 2020 final work RVUs or clinical labor portion of the direct PE RVUs in our calculation to develop the CY 2020 final MP RVUs while maintaining overall PFS budget neutrality.

Similar to the CY 2015 update, the proposed MP RVUs were calculated using specialty-specific malpractice premium data because they represent the expense incurred by practitioners to obtain malpractice insurance as reported by insurers. For CY 2020, the most current malpractice premium data available, with a presumed effective date of no later than December 31, 2017, were obtained from insurers with the largest market share in each state. We identified insurers with the largest market share using the National Association of Insurance Commissioners (NAIC) market share report. This annual report provides state-level market share for entities that provide premium liability insurance (PLI) in a state. Premium data were downloaded from the System for Electronic Rates & Forms Filing Access Interface (SERFF) (accessed from the NAIC website) for participating states. For non-SERFF states, data were downloaded from the state-specific website (if available online) or obtained directly from the state's alternate access to filings. For SERFF states and non-SERFF states with online access to filings, the 2017 market share report was used to select companies. For non-SERFF states without online access to filings, the 2016 market share report was used to identify companies. These were the most current data available during the data collection and acquisition process.

Malpractice insurance premium data were collected from all 50 States, and the District of Columbia. Efforts were made to collect filings from Puerto Rico; however, no recent filings were submitted at the time of data collection and therefore filings from the previous update were used. Consistent with the CY 2015 update, no filings were collected for the other U.S. territories: American Samoa, Guam, Virgin Islands, or Northern Mariana Islands. Malpractice premiums were collected for coverage limits of $1 million/$3 million, mature, claims-made policies (policies covering claims made, rather than those covering losses occurring, during the policy term). A $1 million/$3 million liability limit policy means that the most that would be paid on any claim is $1 million and the most that the policy would pay for claims over the timeframe of the policy is $3 million. Adjustments were made to the premium data to reflect mandatory surcharges for patient compensation funds (PCF, funds used to pay for any claim beyond the state's statutory amount, thereby limiting an individual physician's liability in cases of a large suit) in states where participation in such funds is mandatory.

Premium data were included for all physician and NPP specialties, and all risk classifications available in the collected rate filings. Although premium data were collected from all states, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all states. In previous updates, specialties for which premium data were not available for at least 35 states, and specialties for which there were not distinct risk groups (surgical, non-surgical, and surgical with obstetrics) among premium data in the rate filings, were crosswalked to a similar specialty, either conceptually or based on available premium data. This resulted in not using those premium data because

the 35 state threshold was not met. In this proposed CY 2020 update, we note that the proposed methodological improvement discussed below in this proposed rule expands the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

b. Proposed Methodological Refinements

For the CY 2020 update, we are proposing the following methodological improvements to the development of MP premium data:

(1) Downloading and using a broader set of filings from the largest market share insurers in each state, beyond those listed as ''physician'' and ''surgeon'' to obtain a more comprehensive data set.

(2) Combining minor surgery and major surgery premiums to create the surgery service risk group, which yields a more representative surgical risk factor. In the previous update, only premiums for major surgery were used in developing the surgical risk factor.

(3) Utilizing partial and total imputation to develop a more comprehensive data set when CMS specialty names are not distinctly identified in the insurer filings, which sometimes use unique specialty names.

In instances where insurers report data for some (but not all) specialties that explicitly corresponded to a CMS specialty, where those data were missing, we propose to use partial imputation based on available data to establish what the premiums would likely have been had that specialty been delineated in the filing. In instances where there are no data corresponding to a CMS specialty in the filing, we propose to use total imputation to establish premiums.

For example, if a specialty of Sleep Medicine is listed on the insurer's rate filing, this rate will be matched to the CMS specialty Sleep Medicine (C0). However, if the Sleep Medicine specialty is not listed on the insurer's rate filing, under our proposed methodology, the insurer's rate filing for General Practice would be matched to the CMS specialty of Sleep Medicine (C0). In this example, we believe General Practice is likely to be consistent with the rate that a Sleep Medicine provider would be charged by that insurer. This proposed methodological improvement means that instead of discarding specialty-specific information from some insurers' filings because other insurers lacked that same level of detail, we would instead impute the missing rates at the insurer/specialty level in an effort to utilize as much of the information from the filings as possible.

We are seeking comment on these proposed methodological improvements. Additional technical details are available in our interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' on our website. It is located under the supporting documents section for the CY 2020 PFS proposed rule located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

c. Steps for Calculating Malpractice RVUs

Calculation of the proposed MP RVUs conceptually follows the specialty-weighted approach used in the CY 2015 final rule with comment period (79 FR 67591), along with the above proposed methodological improvements. The specialty-weighted approach bases the MP RVUs for a given service on a weighted average of the risk factors of all specialties furnishing the service. This approach ensures that all specialties furnishing a given service are reflected in the calculation of the MP RVUs. The steps for calculating the proposed MP RVUs are described below.

Step (1): Compute a preliminary national average premium for each specialty.

Insurance rating area malpractice premiums for each specialty are mapped to the county level. The specialty premium for each county is then multiplied by its share of the total U.S. population (from the U.S. Census Bureau's 2013–2017 American Community Survey (ACS) 5-year estimates). This is in contrast to the method used for creating national average premiums for each specialty in the 2015 update; in that update, specialty premiums were weighted by the total RVU per county, rather than by the county share of the total U.S. population. We refer readers to the CY 2016 PFS final rule with comment period (80 FR 70909) for a discussion of why we have adopted a weighting method based on share of total U.S. population. This calculation is then divided by the average MP GPCI across all counties for each specialty to yield a normalized national average premium for each specialty. The specialty premiums are normalized for geographic variation so that the locality cost differences (as reflected by the 2019 GPCIs) would not be counted twice. Without the geographic variation adjustment, the cost differences among fee schedule areas would be reflected once under the methodology used to calculate the MP RVUs and again when computing the service specific payment amount for a given fee schedule area.

Step (2): Determine which premium service risk groups to use within each specialty.

Some specialties had premium rates that differed for surgery, surgery with obstetrics, and non-surgery. These premium classes are designed to reflect differences in risk of professional liability and the cost of malpractice claims if they occur. To account for the presence of different classes in the malpractice premium data and the task of mapping these premiums to procedures, we calculated distinct risk factors for surgical, surgical with obstetrics, and nonsurgical procedures where applicable. However, the availability of data by surgery and non-surgery varied across specialties. Historically, no single approach accurately addressed the variability in premium class among specialties, and we previously employed several methods for calculating average premiums by specialty. These methods are discussed below.

Developing Distinct Service Risk Groups: We determined that there were sufficient data for surgery and non-surgery premiums, as well as sufficient differences in rates between classes for 15 specialties (there were 10 such specialties in the CY 2015 update). These specialties are listed in Table 10. Additionally, as described in the proposed methodological refinements, in some instances, we combined minor surgery and major surgery premiums to create a premium to develop the surgery service risk group, rather than discard minor surgery premium data as was done in the previous update. Therefore, we calculated a national average surgical premium and non-surgical premium for those specialties. For all other specialties (those that are not listed in Table 10) that typically do not distinguish premiums as described above, a single risk factor was calculated, and that specialty risk factor was applied to all services performed by those specialties.

This is consistent with prior practice; however, we have refined the nomenclature to more precisely describe that some specialties are delineated into service risk groups, as is the case for surgical, non-surgical, and surgical with obstetrics, and some specialties are not further delineated into service risk subgroups and are instead referred to as ''All''—meaning that all services performed by that specialty receive the same risk factor.

TABLE 10—PROPOSED SPECIALTIES SUBDIVIDED INTO SERVICE RISK GROUPS

Service risk groups	Specialties
Surgery/No Surgery	Otolaryngology (04), Cardiology (06), Dermatology (07), Gastroenterology (10), Neurology (13), Ophthalmology (18), Urology (34), Geriatric Medicine (38), Nephrology (39), Endocrinology (46), Podiatry (48), Emergency Medicine (93).
Surgery/No Surgery/OB	General Practice (01), Family Practice (08), OB/GYN (16).

Step (3): Calculate a risk factor for each specialty.

The relative differences in national average premiums between specialties are expressed in our methodology as a specialty-level risk factor. These risk factors are calculated by dividing the national average premium for each specialty by the national average premium for the specialty with the lowest premiums for which we had sufficient and reliable data, which remains allergy and immunology (03). For specialties with rate filings that are indicative of sufficient surgical and non-surgical premium data, we recognized those service-risk groups (that is, surgical, and non-surgical) as risk groups of the specialty and we calculated both a surgical and non-surgical risk factor. Similarly, for specialties with rate filings that distinguished surgical premiums with obstetrics, we recognized that service-risk subgroup of the specialty and calculated a separate surgical with obstetrics risk factor.

(a) Technical Component (TC) Only Services

We note that for determining the risk factor for suppliers of TC-only services in the CY 2015 update, we updated the premium data for independent diagnostic testing facilities (IDTFs) that we used in the CY 2010 update. Those data were obtained from a survey conducted by the Radiology Business Management Association (RBMA) in 2009; we ultimately used those data to calculate an updated TC specialty risk factor. We applied the updated TC specialty risk factor to suppliers of TC-only services. In the CY 2015 final rule with comment period (79 FR 67595), RBMA voluntarily submitted updated MP premium information collected from IDTFs in 2014, and requested that we use the data for calculating the CY 2015 MP RVUs for TC-only services. We declined to utilize the data and stated that we believe further study is necessary and we would consider this matter and propose any changes through future rulemaking. We continue to believe that data for a broader set of TC-only services are needed, and are working to acquire a broader set of data.

For CY 2020, we propose to assign a risk factor of 1.00 for TC-only services, which corresponds to the lowest physician specialty-level risk factor. We assigned the risk factor of 1.00 to the TC-only services because we do not have sufficient comparable professional liability premium data for the full range of clinicians that furnish TC-only services. In lieu of comprehensive, comparable data, we propose to assign 1.00, the lowest physician specialty-level risk factor calculated using the updated premium data, as the default minimum risk factor. However, we seek information on the most comparable and appropriate proxy for the broader set of TC-only services for future use, as well as any empirical information that would support assignment of an alternative risk factor for these services.

Table 11 shows the proposed risk factors by specialty type and service risk group.

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TABLE 11: CY 2020 Proposed Risk Factors by Specialty and Service Risk Group

Medicare Specialty Code and Name	2020 Service Risk Group	2020 Risk Factor
01-General practice	NO SURG	1.63
01-General practice	SURG	2.86
01-General practice	OB	3.70
02-General surgery	ALL	6.81
03-Allergy/immunology	ALL	1.00
04-Otolaryngology	NO SURG	1.64
04-Otolaryngology	SURG	3.10
05-Anesthesiology	ALL	2.20
06-Cardiology	NO SURG	1.89
06-Cardiology	SURG	6.06
07-Dermatology	NO SURG	1.16
07-Dermatology	SURG	2.14
08-Family practice	NO SURG	1.63
08-Family practice	SURG	2.58
08-Family practice	OB	3.69
09-Interventional pain management	ALL	2.80
10-Gastroenterology	NO SURG	1.90
10-Gastroenterology	SURG	2.51
11-Internal medicine	ALL	1.76
12-Osteopathic manipulative therapy	ALL	1.00
13-Neurology	NO SURG	2.24
13-Neurology	SURG	9.60
14-Neurosurgery	ALL	9.60
15-Speech language pathology	ALL	1.00
16-Obstetrics/gynecology	NO SURG	1.86
16-Obstetrics/gynecology	SURG	3.72
16-Obstetrics/gynecology	OB	7.81
17-Hospice & palliative care	ALL	1.00
18-Ophthalmology	NO SURG	1.17
18-Ophthalmology	SURG	2.01
19-Oral surgery	ALL	2.41
20-Orthopedic surgery	ALL	5.51
21-Cardiac electrophysiology	ALL	1.89
22-Pathology	ALL	1.51
23-Sports medicine	ALL	1.66
24-Plastic and reconstructive surgery	ALL	4.97
25-Physical medicine and rehabilitation	ALL	1.38
26-Psychiatry	ALL	1.02
27-Geriatric psychiatry	ALL	1.02
28-Colorectal surgery	ALL	3.57
29-Pulmonary disease	ALL	2.06
30-Diagnostic radiology	ALL	2.25
31-Intensive cardiac rehab	ALL	1.89
32-Anesthesiologist assistants	ALL	0.60
33-Thoracic surgery	ALL	6.43
34-Urology	NO SURG	1.75
34-Urology	SURG	3.07
35-Chiropractic	ALL	0.52
36-Nuclear medicine	ALL	1.23
37-Pediatric medicine	ALL	1.78

Medicare Specialty Code and Name	2020 Service Risk Group	2020 Risk Factor
38-Geriatric medicine	NO SURG	1.49
38-Geriatric medicine	SURG	2.34
39-Nephrology	NO SURG	1.67
39-Nephrology	SURG	2.50
40-Hand surgery	ALL	4.42
41-Optometry	ALL	0.17
42-Certified nurse midwife	ALL	2.06
43-CRNA	ALL	0.68
44-Infectious disease	ALL	2.11
45-Mammography screening center	ALL	1.00
46-Endocrinology	NO SURG	1.59
46-Endocrinology	SURG	2.67
47-Independent diagnostic testing facility	ALL	1.00
48-Podiatry	NO SURG	1.27
48-Podiatry	SURG	2.10
62-Psychologist	ALL	1.00
63-Portable x-ray supplier	ALL	1.00
64-Audiologist	ALL	1.00
65-Physical therapist	ALL	1.00
66-Rheumatology	ALL	1.63
67-Occupational therapist	ALL	1.00
68-Clinical psychologist	ALL	1.00
69-Clinical laboratory	ALL	1.00
70-Multispecialty clinic or group practice	ALL	2.10
71-Registered dietician/nutrition professional	ALL	1.00
72-Pain management	ALL	2.77
75-Slide preparation facilities	ALL	1.00
76-Peripheral vascular disease	ALL	6.75
77-Vascular surgery	ALL	6.75
78-Cardiac surgery	ALL	6.06
79-Addiction medicine	ALL	1.00
80-Licensed clinical social worker	ALL	1.00
81-Critical care (intensivists)	ALL	2.27
82-Hematology	ALL	1.79
83-Hematology/oncology	ALL	1.85
84-Preventive medicine	ALL	1.38
85-Maxillofacial surgery	ALL	2.61
86-Neuropsychiatry	ALL	1.02
90-Medical oncology	ALL	1.86
91-Surgical oncology	ALL	6.46
92-Radiation oncology	ALL	2.03
93-Emergency medicine	NO SURG	3.00
93-Emergency medicine	SURG	4.92
94-Interventional radiology	ALL	2.76
98-Gynecologist/oncologist	ALL	3.72
99-Unknown physician specialty	ALL	2.10
C0-Sleep medicine	ALL	1.61
C0-Sleep medicine	ALL	1.61
C3-Interventional cardiology	ALL	5.92
C6-Hospitalist	ALL	2.13
C7-Advanced heart failure & transplant cardiology	ALL	6.06

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Step (4): Calculate malpractice RVUs for each CPT/HCPCS code.

Resource-based MP RVUs were calculated for each CPT/HCPCS code that has work or PE RVUs. The first step was to identify the percentage of services furnished by each specialty for each respective CPT/HCPCS code. This

percentage was then multiplied by each respective specialty's risk factor as calculated in Step 3. The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk factor reflecting the weighted malpractice costs across all specialties furnishing that procedure. The service specific risk factor was multiplied by the greater of the work RVU or clinical labor portion of the direct PE RVU for that service, to reflect differences in the complexity and risk-of-service between services.

Low volume service codes: As we discussed above in this proposed rule, for low volume services code, we finalized the proposal in the CY 2018 PFS final rule (82 FR 53000 through 53006) to apply the list of expected specialties instead of the claims-based specialty mix for low volume services to address stakeholder concerns about the year to year variability in PE and MP RVUs for low volume services (which also includes no volume services); these are defined as codes that have 100 allowed services or fewer. These service-level overrides are used to determine the specialty for low volume procedures for both PE and MP.

In the CY 2018 PFS final rule (82 FR 53000 through 53006), we also finalized our proposal to eliminate general use of an MP-specific specialty-mix crosswalk for new and revised codes. However, we indicated that we would continue to consider, in conjunction with annual recommendations, specific recommendations regarding specialty mix assignments for new and revised codes, particularly in cases where coding changes are expected to result in differential reporting of services by specialty, or where the new or revised code is expected to be low-volume. Absent such information, the specialty mix assumption for a new or revised code would derive from the analytic crosswalk in the first year, followed by the introduction of actual claims data, which is consistent with our approach for developing PE RVUs.

For CY 2020, we are soliciting public comment on the list of expected specialties. We also note that the list has been updated to include a column indicating if a service is identified as a low volume service for CY 2020, and therefore, whether or not the service-level override is being applied for CY 2020. The proposed list of codes and expected specialties is available on our website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Step (5): Rescale for budget neutrality.

The statute requires that changes to fee schedule RVUs must be budget neutral. Thus, the last step is to adjust for relativity by rescaling the proposed MP RVUs so that the total proposed resource based MP RVUs are equal to the total current resource based MP RVUs scaled by the ratio of the pools of the proposed and current MP and work RVUs. This scaling is necessary to maintain the work RVUs for individual services from year to year while also maintaining the overall relationship among work, PE, and MP RVUs.

Specialties Excluded from Ratesetting Calculation: In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we discuss specialties that are excluded from ratesetting for the purposes of calculating PE RVUs. We are proposing to treat those excluded specialties in a consistent manner for the purposes of calculating MP RVUs. We note that all specialties are included for purposes of calculating the final BN adjustment. The list of specialties excluded from the ratesetting calculation for the purpose of calculating the PE RVUs that we are proposing to also exclude for the purpose of calculating MP RVUs is available in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units. The proposed resource based MP RVUs are shown in Addendum B, which is available on the CMS website under the downloads section of the CY 2020 PFS rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

Because a different share of the resources involved in furnishing PFS services is reflected in each of the three fee schedule components, implementation of the resource-based MP RVU update will have much smaller payment effects than implementing updates of resource-based work RVUs and resource-based PE RVUs. On average, work represents about 50.9 percent of payment for a service under the fee schedule, PE about 44.8 percent, and MP about 4.3 percent. Therefore, a 25 percent change in PE RVUs or work RVUs for a service would result in a change in payment of about 11 to 13 percent. In contrast, a corresponding 25 percent change in MP values for a service would yield a change in payment of only about 1 percent. Estimates of the effects on payment by specialty type can be found in section VI. of this proposed rule, Regulatory Impact Analysis.

Additional information on our proposed methodology for updating the MP RVUs is available in the ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' which is available on the CMS website under the downloads section of the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

D. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)). We discuss the localities established under the PFS below in this section. Although the statute requires that the PE and MP GPCIs reflect full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2017. Section 50201 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the statute to extend the 1.0 floor for the work GPCIs through CY 2019 (that is, for services furnished no later than December 31, 2019).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CYs 2017 and 2018, we are proposing to phase in ½ of the latest GPCI adjustment in CY 2020.

We have completed a review of the GPCIs and are proposing new GPCIs in this proposed rule. We also calculate a geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each PFS localities work, PE and MP expense GPCIs using the national GPCI cost share weights. While we do not actually use GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service would deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 50201 of the BBA of 2018 extended the 1.0 work GPCI floor for services furnished only through December 31, 2019. Therefore, the proposed CY 2020 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. However, as required by sections 1848(e)(1)(G) and (I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2020. See Addenda D and E to this proposed rule for the CY 2020 proposed GPCIs and summarized proposed GAFs available on the CMS website under the supporting documents section of the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

2. Payment Locality Background

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments under this system largely reflected the charging patterns of physicians, which resulted in large differences in payment for physicians' services among types of services, physician specialties and geographic payment areas.

Local Medicare carriers initially established 210 payment localities, to reflect local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. In 1994, we undertook a study that culminated in a comprehensive locality revision (based on locality resource cost differences as reflected by the GPCIs) that we implemented in 1997. The development of the current locality structure is described in detail in the CY 1997 PFS final rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494). The revised locality structure reduced the number of localities from 210 to 89, and increased the number of statewide localities from 22 to 34.

Section 220(h) of the Protecting Access to Medicare Act (PAMA) (Pub. L. 113–93, enacted April 1, 2014) required modifications to the payment localities in California for payment purposes beginning with 2017. As a result, in the CY 2017 PFS final rule (81 FR 80265 through 80268) we established 23 additional localities, increasing the total number of PFS localities from 89 to 112. The 112 payment localities include 34 statewide areas (that is, only one locality for the entire state) and 75 localities in the other 16 states, with 10 states having two localities, two states having three localities, one state having four localities, and three states having five or more localities. The remainder of the 112 PFS payment localities are comprised as follows: The combined District of Columbia, Maryland, and Virginia suburbs; Puerto Rico; and the Virgin Islands. We note that the localities generally represent a grouping of one or more constituent counties.

The current 112 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate locality adjusted payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), changes to the PFS locality structure would generally result in changes that are budget neutral within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74384 through 74386) for further discussion regarding additional information about locality configuration considerations.

3. GPCI Update

As required by the statute, we developed GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). We describe the data sources and methodologies we use to calculate each of the three GPCIs below in this section. Additional information on the CY 2020 GPCI update is available in an interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule,'' on our website located under the supporting documents section for the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

a. Work GPCIs

The work GPCIs are designed to reflect the relative cost of physician labor by Medicare PFS locality. As required by statute, the work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the ''long form'' was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries). For the CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a

replacement for the 2006 through 2008 data to compute the work GPCIs; and for the CY 2017 GPCI update, we used updated BLS OES data (2011 through 2014) as a replacement for the 2009 through 2011 data to compute the work GPCIs.

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES data continue to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed below, the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2020 GPCI update, we used updated BLS OES data (2014 through 2017) as a replacement for the 2011 through 2014 data to compute the work GPCIs.

b. Practice Expense (PE) GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising PEs (not including MP expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085). The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the equipment, supplies and other miscellaneous expense cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2017), we used 2011 through 2014 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As discussed previously in this section, because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2020 GPCI update, we used updated BLS OES data (2014 through 2017) as a replacement for the 2011 through 2014 data for purposes of calculating the employee wage component and purchased service index component of the PE GPCI. In calculating the proposed CY 2020 GPCI update, for the office rent index component of the PE GPCI we used the most recently available, 2013 through 2017, American Community Survey (ACS) 5-year estimates as a replacement for the 2009 through 2013 ACS data.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for $1 million to $3 million mature claims-made policies (policies for claims made rather than losses occurring during the policy term). For the CY 2017 GPCI update, we used 2014 and 2015 malpractice premium data. The proposed CY 2020 MP GPCI update reflects premium data presumed in effect as of December 30, 2017. We note that we finalized a few technical refinements to the MP GPCI methodology in CY 2017, and refer readers to the CY 2017 PFS final rule (81 FR 80270) for additional discussion.

d. GPCI Cost Share Weights

For CY 2020 GPCIs, we are proposing to continue to use the current cost share weights for determining the PE GPCI values and locality GAFs. We refer readers to the CY 2014 PFS final rule with comment period (78 FR 74382 through 74383), for further discussion regarding the 2006-based MEI cost share weights revised in CY 2014 that we also finalized for use in the CY 2017 GPCI update.

The proposed GPCI cost share weights for CY 2020 are displayed in Table 12.

TABLE 12—PROPOSED COST SHARE WEIGHTS FOR CY 2020 GPCI UPDATE

Expense category	Current cost share weight (%)	Proposed CY 2020 cost share weight (%)
Work	50.866	50.866
Practice Expense	44.839	44.839
—Employee Compensation	16.553	16.553
—Office Rent	10.223	10.223
—Purchased Services	8.095	8.095
—Equipment, Supplies, Other	9.968	9.968
Malpractice Insurance	4.295	4.295
Total	100.000	100.000

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier states effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are ''frontier counties,'' which are those that

have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System (IPPS) final rule (75 FR 50160 through 50161). There are no changes in the states identified as Frontier States for the CY 2020 PFS proposed rule. The qualifying states are: Montana; Wyoming; North Dakota; South Dakota; and Nevada. In accordance with statute, we would apply a 1.0 PE GPCI floor for these states in CY 2020.

f. Methodology for Calculating GPCIs in the U.S. Territories

Prior to CY 2017, for all the island territories other than Puerto Rico, the lack of comprehensive data about unique costs for island territories had minimal impact on GPCIs because we used either the Hawaii GPCIs (for the Pacific territories: Guam; American Samoa; and Northern Mariana Islands) or used the unadjusted national averages (for the Virgin Islands). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, in the CY 2017 PFS final rule (81 FR 80268 through 80270), we finalized a policy to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. We refer readers to the CY 2017 PFS final rule for a comprehensive discussion of this policy.

g. California Locality Update to the Fee Schedule Areas Used for Payment Under Section 220(h) of the Protecting Access to Medicare Act

Section 220(h) of the PAMA added a new section 1848(e)(6) to the Act that modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Prior to CY 2017, the fee schedule areas used for payment in California were based on the revised locality structure that was implemented in 1997 as previously discussed. Beginning in CY 2017, section 1848(e)(6)(A)(i) of the Act required that the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and section 1848(e)(6)(A)(ii) of the Act required that all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California's locality structure increased its number of localities from 9 under the current locality structure to 27 under the MSA-based locality structure; although for the purposes of payment the actual number of localities under the MSA-based locality structure is 32. We refer readers to the CY 2017 PFS final rule (81 FR 80267) for a detailed discussion of this operational consideration.

Section 1848(e)(6)(D) of the Act defined transition areas as the fee schedule areas for 2013 that were the rest-of-state locality, and locality 3, which was comprised of Marin County, Napa County, and Solano County. Section 1848(e)(6)(B) of the Act specified that the GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2022, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure. That is, the GPCI values applicable for these areas during this transition period are a blend of what the GPCI values would have been for California under the current locality structure, and what the GPCI values would be for California under the MSA-based locality structure. For example, in CY 2020, which represents the fourth year, the applicable GPCI values for counties that were previously in rest-of-state or locality 3 and are now in MSAs are a blend of ⅔ of the GPCI value calculated for the year under the MSA-based locality structure, and ⅓ of the GPCI value calculated for the year under the current locality structure. The proportions continue to shift by ⅙ in each subsequent year so that, by CY 2021, the applicable GPCI values for counties within transition areas are a blend of ⅚ of the GPCI value for the year under the MSA-based locality structure, and ⅙ of the GPCI value for the year under the current locality structure. Beginning in CY 2022, the applicable GPCI values for counties in transition areas are the values calculated solely under the new MSA-based locality structure. For clarity, we reiterate that this incremental phase-in is only applicable to those counties that are in transition areas that are now in MSAs, which are only some of the counties in the 2013 California rest-of state locality and locality 3.

Additionally, section 1848(e)(6)(C) of the Act establishes a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. The eight counties that are not within transition areas are: Orange; Los Angeles; Alameda; Contra Costa; San Francisco; San Mateo; Santa Clara; and Ventura counties.

For the purposes of calculating budget neutrality and consistent with the PFS budget neutrality requirements as specified under section 1848(c)(2)(B)(ii)(II) of the Act, we finalized the policy to start by calculating the national GPCIs as if the current localities are still applicable nationwide; then, for the purposes of payment in California, we override the GPCI values with the values that are applicable for California consistent with the requirements of section 1848(e)(6) of the Act. This approach is consistent with the implementation of the GPCI floor provisions that have previously been implemented—that is, as an after-the-fact adjustment that is implemented for purposes of payment after both the GPCIs and PFS budget neutrality have already been calculated.

Additionally, section 1848(e)(1)(C) of the Act requires that, if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be ½ of the adjustment that otherwise would be made. However, since section 1848(e)(6)(B) of the Act provides for a gradual phase in of the GPCI values under the new MSA-based locality structure for California, specifically in one-sixth increments over 6 years, if we were to also apply the requirement to phase in ½ of the adjustment in year 1 of the GPCI update then the first year increment would effectively be 1/12. Therefore, in CY 2017, we finalized a policy that the requirement at section 1848(e)(1)(C) of the Act to phase in ½ of the adjustment in year 1 of the GPCI update would not apply to counties that were previously in the rest-of-state or locality 3 and are now in MSAs that are subject to the blended phase-in as described above in this section. We reiterate that this is only applicable through CY 2021 since, beginning in CY 2022, the GPCI values for such areas in an MSA would be fully based on the values calculated under the new MSA-based locality structure for California. For a comprehensive discussion of this provision, transition areas, and operational considerations, we refer readers to the CY 2017 PFS final rule (81 FR 80265 through 80268).

h. Refinements to the GPCI Methodology

In the process of calculating GPCIs for the purposes of this proposed rule, we identified two technical refinements to the methodology that yield improvements over the current method; these refinements are applicable to the work GPCI and the employee wage index and purchased services index components of the PE GPCI. We are proposing to weight by total employment when computing county median wages for each occupation code which addresses the fact that the occupation wage can vary by industry within a county. Additionally, we are also proposing to use a weighted average when calculating the final county-level wage index; this removes the possibility that a county index would imply a wage of 0 for any occupation group not present in the county's data. These proposed methodological refinements yield improved mathematical precision. Additional information on the GPCI methodology and the proposed refinements are available in the interim report, ''Interim Report for the CY 2020 Update of GPCIs and MP RVUs for the Medicare Physician Fee Schedule'' on our website located under the supporting documents section of the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

i. Proposed GPCI Update Summary

As explained above in the Background section above, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2020 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, are displayed in Addenda D and E to this proposed rule available on our website under the supporting documents section of the CY 2020 PFS proposed rule web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

E. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.N. of this proposed rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the RUC, MedPAC, and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE declines. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the

same service between different sites of service.

- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare and Medicaid Service, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed approximately 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule (76 FR 73052 through 73055) (hereinafter referred to as the CY 2012 PFS final rule with comment period). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the CY 2013 PFS final rule with comment period), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to the CY 2009 PFS proposed rule), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time).

In the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 final rule with comment period (80 FR 70886) (hereinafter referred to as the CY 2016 PFS final rule with comment period), we finalized for review a list of potentially misvalued services, which included eight codes in the neurostimulators analysis-programming family (CPT codes 95970–95982). We also finalized as potentially misvalued 103 codes identified through our screen of high expenditure services across specialties.

In the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements final rule (81 FR 80170) (hereinafter referred to as the CY 2017 PFS final rule), we finalized for review a list of potentially misvalued services, which included eight codes in the end-stage renal disease home dialysis family (CPT codes 90963–90970). We also finalized as potentially misvalued 19 codes

identified through our screen for 0-day global services that are typically billed with an evaluation and management (E/M) service with modifier 25.

In the CY 2018 PFS final rule, we finalized arthrodesis of sacroiliac joint (CPT code 27279) as potentially misvalued. Through the use of comment solicitations with regard to specific codes, we also examined the valuations of other services, in addition to, new potentially misvalued code screens (82 FR 53017 through 53018).

3. CY 2020 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received three submissions that nominated codes for review under the potentially misvalued code initiative, prior to our February 10, 2019 deadline. In addition to three public nominations, CMS also nominated one additional code for review.

One commenter requested that CMS consider CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*) for nomination as potentially misvalued. We note that these two CPT codes were recently reviewed within a family of 13 similar codes. Our review of these codes and our rationale for finalizing the current values are discussed extensively in the CY 2019 PFS final rule (83 FR 59517). For CPT code 10021, the RUC recommended a 32 percent reduction from its previous physician time and a 5 percent reduction in the work RVU. The commenter disagreed with this change and stated that there was a change in intensity of the procedure now as compared to what it was in 1995 when this code was last evaluated. The commenter also stated that there was a change in intensity of the work performed due to use of more complicated equipment, more stringent specimen sampling that allow for extensive examination of smaller and deeper lesions within the body. The commenter disagreed with the CMS' crosswalked CPT code 36440 (*Push blood transfusion, patient 2 years or younger*) and presented CPT codes 40490 (*Biopsy of lip*) and 95865 (*Needle measurement and recording of electrical activity of muscles of voice box*) as more appropriate crosswalks.

Another commenter requested that CMS consider HCPCS code G0166 (*External counterpulsation, per treatment session*) as potentially misvalued. This code was reviewed for the CY 2019 PFS final rule (83 FR 59578), and the work RVU and direct PE inputs as recommended by the AMA RUC were finalized by CMS. We finalized the valuation of this code with no refinements. However, the commenter noted that the PE inputs that were considered for this code did not fully reflect the total resources required to deliver the service. We will review the commenter's submission of additional new data and public comments received in combination with what was previously presented in the CY 2019 PFS final rule.

CMS nominated CPT code 76377 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation*) as potentially misvalued. CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*) was reviewed by the AMA RUC at the April 2018 RUC meeting. However, CPT code 76377, which is very similar to CPT code 76376, was not reviewed, and is likely now misvalued, in light of the similarities between the two codes. The specialty societies noted that the two codes are different because they are utilized by different patient populations (as evidenced by the ICD–10 diagnoses); however, we view both codes to be similar enough that CPT code 76377 should be reviewed to maintain relativity in the code family.

We are proposing the aforementioned public and CMS nominated codes as potentially misvalued and welcome public comment on these codes.

Another commenter provided information to CMS in which they stated that the work involved in furnishing services represented by the office/outpatient evaluation and management (E/M) code set (CPT codes 99201–99215) has changed sufficiently to warrant revaluation. Specifically, the commenter stated that these codes have not been reviewed in over 12 years and in that time have suffered passive devaluation as more and more procedures and other services have been added to the CPT code set, which are subsequently valued in a budget neutral manner, through notice and comment rulemaking, on the Medicare PFS. The commenter also stated that re-evaluation of these codes is critical to the success

of CMS' objective of advancing value-based care through the introduction of advanced alternative payment models (APMs) as these APMs rely on the underlying E/M codes as the basis for payment or reference price for bundled payments.

We acknowledge the points made by the commenter, and continue to consider the best ways to recognize the significant changes in healthcare practice as discussed by the commenter. We agree, in principle, that the existing set of office/outpatient E/M CPT codes may not be correctly valued. In recent years, we have specifically considered how best to update and revalue the E/M codes, which represent a significant proportion of PFS expenditures, and have also engaged in ongoing dialogue with the practitioner community. In the CY 2019 PFS proposed and final rules, in part due to these ongoing stakeholder discussions, we proposed and finalized changes to E/M payment and documentation requirements to implement policy objectives focused on reducing provider documentation burden (83 FR 59625). Concurrently, the CPT Editorial Panel, under similar burden reduction guiding principles, convened a workgroup and proposed to refine and revalue the existing E/M office/outpatient code set. We thank the commenter for the views represented in their comment. As stated earlier in this section, we agree in principle that the existing set of office/outpatient E/M CPT codes may not be correctly valued, and therefore, we will continue to consider opportunities to revalue these codes, in light of their significance to payment for services billed under Medicare.

Table 13 lists the HCPCS and CPT codes that we are proposing as potentially misvalued.

TABLE 13—HCPCS AND CPT CODES PROPOSED AS POTENTIALLY MISVALUED

CPT/HCPCS code	Short description
10005	Fna bx w/us gdn 1st les.
10021	Fna bx w/o img gdn 1st les.
76377	3d render w/intrp postproces.
G0166	Extrnl counterpulse, per tx.

F. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in this rule and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, *see* the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and in 42 CFR 410.78 and 414.65.

1. Adding Services to the List of Medicare Telehealth Services

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us. Under this process, we assign any submitted request to add to the list of telehealth services to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the proposed additions described later in this section, can be located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Historically, requests to add services to the list of Medicare telehealth services had to be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. However, beginning in CY 2019 we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC. For example, to be considered during PFS rulemaking for CY 2021, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2020. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the list of Medicare telehealth services, requesters should be advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the list of Medicare telehealth services, including where to mail these requests, *see* our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

2. Requests To Add Services to the List of Telehealth Services for CY 2020

Under our current policy, we add services to the telehealth list on a Category 1 basis when we determine that they are similar to services on the existing telehealth list for the roles of,

and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

We did not receive any requests from the public for additions to the Medicare Telehealth list for CY 2020. We believe that the vast majority of services under the PFS that can be appropriately furnished as Medicare telehealth services have already been added to the list.

However, there are three HCPCS G-codes describing new services being proposed in section II.H. of this rule for CY 2020 which we believe are sufficiently similar to services currently on the telehealth list to be added on a Category 1 basis. Therefore, we are proposing to add the face-to-face portions of the following services to the telehealth list on a Category 1 basis for CY 2020:

- HCPCS code GYYY1: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code GYYY2: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code GYYY3: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

Similar to our addition of the required face-to-face visit component of TCM services to the Medicare Telehealth list in the CY 2014 PFS final rule with comment period (78 FR 74403), since HCPCS codes GYYY1, GYYY2, and GYYY3 include face-to-face psychotherapy services, we believe that the face-to-face portions of these services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under Category 1. Specifically, we believe that the psychotherapy portions of the bundled codes are similar to the psychotherapy codes described by CPT codes 90832 and 90853, which are currently on the Medicare telehealth services list. We note that like certain other non-face-to-face PFS services, the other components of HCPCS codes GYYY1–3 describing care coordination are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of HCPCS codes GYYY1–3 are similar to other telehealth services. Were these components of HCPCS codes GYYY1–3 separately billable, they would not need to be on the Medicare telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology.

As discussed in the CY 2019 PFS final rule (83 FR 59496), we note that section 2001(a) of the SUPPORT Act (Pub. L. 115–271, October 24, 2018) amended section 1834(m) of the Act, adding a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, for individuals diagnosed with a substance use disorder (SUD) for the purpose of treating the SUD or a co-occurring mental health disorder. Section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. Section 2001(a) of the SUPPORT Act additionally amended section 1834(m) of the Act to require that no originating site facility fee will be paid in instances when the individual's home is the originating site. We believe that adding HCPCS codes GYYY1, GYYY2, and GYYY3 will complement the existing policies related to flexibilities in treating SUDs under Medicare Telehealth.

We note that we welcome public nominations for additions to the Medicare telehealth list. More information on the nomination process is posted under the Telehealth section of the CMS website, which can be accessed at the following web address *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

G. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Overview

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The Centers for Disease Control and Prevention (CDC) estimated 47,000 overdose deaths were from opioids in 2017 and 36 percent of those deaths were from prescription opioids.[1] OUD has become a public health crisis. On October 26, 2017, Acting Health and Human Services Secretary, Eric D. Hargan declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[2] This public health emergency was renewed by Secretary Alex M. Azar II on January 24, 2018, April 24, 2018, July 23, 2018, and October 21, 2018, January 17, 2019 and most recently, on April 19, 2019.[3]

The Medicare population, including individuals who are eligible for both Medicare and Medicaid, has the fastest growing prevalence of OUD compared to the general adult population, with more than 300,000 beneficiaries diagnosed with OUD in 2014.[4] An effective treatment for OUD is known as medication-assisted treatment (MAT). The Substance Abuse and Mental Health Services Administration (SAMHSA) defines MAT as the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder (42 CFR 8.2). Currently, Medicare covers medications for MAT, including buprenorphine, buprenorphine-naloxone combination products, and extended-release injectable naltrexone under Part B or Part D, but does not cover methadone. Medicare also covers counseling and behavioral therapy services that are reasonable and necessary and furnished by practitioners that can bill and receive payment under Medicare.

Historically, Medicare has not covered methadone for MAT because of the unique manner in which this drug is dispensed and administered. Medicare Part B covers physician-administered drugs, drugs used in

[1] *https://www.cdc.gov/drugoverdose/data/index.html.*

[2] *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[3] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19apr2019.aspx.*

[4] *https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238.*

conjunction with durable medical equipment, and certain other statutorily specified drugs. Medicare Part D covers drugs that are dispensed upon a prescription by a pharmacy. Methadone for MAT is not a drug administered by a physician under the incident to benefit like other MAT drugs (that is, implanted buprenorphine or injectable extended-release naltrexone) and therefore has not previously been covered by Medicare Part B. Methadone for MAT is also not a drug dispensed by a pharmacy like certain other MAT drugs (that is buprenorphine or buprenorphine-naloxone combination products) and therefore is not covered under Medicare Part D. Methadone for MAT is a schedule II controlled substance that is highly regulated because it has a high potential for abuse which may lead to severe psychological or physical dependence. As a result, methadone for MAT can only be dispensed and administered by an opioid treatment program (OTP) as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. Additionally, OTPs, which are healthcare entities that focus on providing MAT for people diagnosed with OUD, were not previously entities that could bill and receive payment from Medicare for the services they furnish. Therefore, there has historically been a gap in Medicare coverage of MAT for OUD since methadone (one of the three FDA-approved drugs for MAT) has not been covered.

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018) added a new section 1861(jjj) to the Act, establishing a new Part B benefit category for OUD treatment services furnished by an OTP beginning on or after January 1, 2020. Section 1861(jjj)(1) of the Act defines OUD treatment services as items and services furnished by an OTP (as defined in section 1861(jjj)(2)) for treatment of OUD. Section 2005 of the SUPPORT Act also amended the definition of ''medical and other health services'' in section 1861(s) of the Act to provide for coverage of OUD treatment services and added a new section 1834(w) to the Act and amended section 1833(a)(1) of the Act to establish a bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020.

OTPs must have a current, valid certification from SAMHSA to satisfy the Controlled Substances Act registration requirement under 21 U.S.C. 823(g)(1). To obtain SAMHSA certification, OTPs must have a valid accreditation by an accrediting body approved by SAMHSA, and must be certified by SAMHSA as meeting federal opioid treatment standards in 42 CFR 8.12. There are currently about 1,700 OTPs nationwide.[5] All states except Wyoming have OTPs. Approximately 74 percent of patients receiving services from OTPs receive methadone for MAT, with the vast majority of the remaining patients receiving buprenorphine.[6]

Many payers currently cover MAT services for treatment of OUD. Medicaid [7] is one of the largest payers of medications for substance use disorder (SUD), including methadone for MAT provided in OTPs.[8] OUD treatment services and MAT are also covered by other payers such as TRICARE and private insurers. TRICARE established coverage and payment for MAT and OUD treatment services furnished by OTPs in late 2016 (81 FR 61068). In addition, as discussed in the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020'' proposed rule, many qualified health plans covered MAT medications for plan year 2018 (84 FR 285).

In the CY 2019 PFS final rule (83 FR 59497), we included a Request for Information (RFI) to solicit public comments on the implementation of the new Medicare benefit category for OUD treatment services furnished by OTPs established by section 2005 of the SUPPORT Act. We received 9 public comments. Commenters were generally supportive of the new benefit and expanding access to OUD treatment for Medicare beneficiaries. We received feedback that the bundled payments to OTPs should recognize the intensity of services furnished in the initiation stages, durations of care, the needs of patients with more complex needs, costs of emerging technologies, and use of peer support groups. We also received feedback that costs associated with care coordination among the beneficiary's practitioners should be included in the bundled payment given the myriad of health issues beneficiaries with OUD face. We considered this feedback as we developed our proposals for implementing the new benefit category for OUD treatment services furnished by OTPs and the proposed bundled payments for these services.

To implement section 2005 of the SUPPORT Act, we are proposing to establish rules to govern Medicare coverage of and payment for OUD treatment services furnished in OTPs. In the following discussion, we propose to establish definitions of OUD treatment services and OTP for purposes of the Medicare Program. We also propose a methodology for determining Medicare payment for such services provided by OTPs. We are proposing to codify these policies in a new section of the regulations at § 410.67. For a discussion about Medicare enrollment requirements and the proposed program integrity approach for OTPs, we refer readers to section III.H. Medicare Enrollment of Opioid Treatment Programs, in this proposed rule.

2. Proposed Definitions

a. Opioid Use Disorder Treatment Services

The SUPPORT Act amended section 1861 of the Act by adding a new subsection (jjj)(1) that defines ''opioid use disorder treatment services'' as the items and services that are furnished by an OTP for the treatment of OUD, as set forth in subparagraphs (A) through (F) of section 1861(jjj)(1) of the Act which include:

- Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355) for use in the treatment of OUD;
- Dispensing and administration of such medications, if applicable;
- Substance use counseling by a professional to the extent authorized under state law to furnish such services;
- Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under state law);
- Toxicology testing; and
- Other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

As described previously, section 1861(jjj)(1)(A) of the Act defines covered OUD treatment services to include oral,

[5] *https://dpt2.samhsa.gov/treatment/directory.aspx.*

[6] *https://wwwdasis.samhsa.gov/dasis2/nssats.htm.*

[7] Medicaid provides health care coverage to 65.9 million Americans, including low-income adults, children, pregnant women, elderly adults and people with disabilities. Medicaid is administered by states, according to federal requirements, and is funded jointly by states and the federal government. States have the flexibility to administer the Medicaid program to meet their own state needs within the Medicaid program parameters set forth in federal statute and regulations. As a result, there is variation in how each state implements its programs.

[8] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

injected, and implanted opioid agonist and antagonist medications approved by FDA under section 505 of the FFDCA for use in the treatment of OUD. There are three drugs currently approved by the FDA for the treatment of opioid dependence: Buprenorphine, methadone, and naltrexone.[9] FDA notes that all three of these medications have been demonstrated to be safe and effective in combination with counseling and psychosocial support and that those seeking treatment for an OUD should be offered access to all three options as this allows providers to work with patients to select the medication best suited to an individual's needs.[10] Each of these medications is discussed below in more detail.

Buprenorphine is FDA-approved for acute and chronic pain in addition to opioid dependence. It is listed by the Drug Enforcement Administration (DEA) as a Schedule III controlled substance because of its moderate to low potential for physical and psychological dependence.[11] [12] The medication's partial agonist properties allow for its use in opioid replacement therapy, which is a process of treating OUD by using a substance, for example, buprenorphine or methadone, to substitute for a stronger full agonist opioid.[13] Buprenorphine drug products that are currently FDA-approved and marketed for the treatment of opioid dependence include oral buprenorphine and naloxone [14] films and tablets, an extended-release buprenorphine injection for subcutaneous use, and a buprenorphine implant for subdermal administration.[15] In most patients with opioid dependence, the initial oral dose is 2 to 4 mg per day with a maintenance dose of 8–12 mg per day.[16] Dosing for the extended-release injection is 300 mg monthly for the first 2 months followed by a maintenance dose of 100 mg monthly.[17] The extended-release injection is indicated for patients who have initiated treatment with an oral buprenorphine product for a minimum of 7 days.[18] The buprenorphine implant consists of four rods containing 74.2 mg of buprenorphine each, and provides up to 6 months of treatment for patients who are clinically stable on low-to-moderate doses of an oral buprenorphine-containing product.[19] Currently, federal regulations permit buprenorphine to be prescribed or dispensed by qualifying physicians and qualifying other practitioners at office-based practices and dispensed in OTPs.[20] [21]

Methadone is FDA-approved for management of severe pain in addition to opioid dependence. It is listed by the DEA as a Schedule II controlled substance because of its high potential for abuse, with use potentially leading to severe psychological or physical dependence.[22] [23] Methadone drug products that are FDA-approved for the treatment of opioid dependence include oral methadone concentrate and tablets.[24] In patients with opioid dependence, the total daily dose of methadone on the first day of treatment should not ordinarily exceed 40 mg, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence, with clinical stability generally achieved at doses between 80 to 120 mg/day.[25] By law, methadone can only be dispensed through an OTP certified by SAMHSA.[26]

Naltrexone is FDA-approved to treat alcohol dependence in addition to opioid use disorder.[27] Unlike buprenorphine and methadone, which activate opioid receptors, naltrexone binds and blocks opioid receptors and reduces opioid cravings.[28] Therefore, naltrexone is not a scheduled substance; there is no abuse and diversion potential with naltrexone.[29] [30] The naltrexone drug product that is FDA-approved for the treatment of opioid dependence is an extended-release, intramuscular injection.[31] The recommended dose is 380 mg delivered intramuscularly every 4 weeks or once a month after the patient has achieved an opioid-free duration of a minimum of 7–10 days.[32] Naltrexone can be prescribed by any health care provider who is licensed to prescribe medications.[33]

We propose that the OUD treatment services that may be furnished by OTPs include the first five items and services listed in the statutory definition described above, specifically the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing. We also propose to use our discretion under section 1861(jjj)(1)(F) of the Act to include other items and services that the Secretary determines are appropriate to include the use of telecommunications for certain services, as discussed later in this section. We propose to codify this definition of OUD treatment services furnished by OTPs at § 410.67(b). As part of this definition, we also propose to specify that an OUD treatment service is an item or service that is furnished by an OTP that meets the applicable requirements to participate in the Medicare Program and receive payment.

We seek comment on any other items and services (not including meals or transportation as they are statutorily prohibited) currently covered and paid for under Medicare Part B when furnished by Medicare-enrolled providers/suppliers that the Secretary should consider adding to this definition, including any evidence supporting the impact of the use of such items and services in the treatment of OUD and enumeration of their costs. We are particularly interested in public feedback on whether intake activities, which may include services such as an initial physical examination, initial assessments and preparation of a treatment plan, as well as periodic assessments, should be included in the definition of OUD treatment services. Additionally, we understand that while the current FDA-approved medications under section 505 of the FFDCA for the treatment of OUD are opioid agonists and antagonist medications, other

[9] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[10] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[11] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[12] *https://www.dea.gov/drug-scheduling.*

[13] *https://www.ncbi.nlm.nih.gov/books/NBK459126/.*

[14] Naloxone is added to buprenorphine in order to reduce its abuse potential and limit diversion.

[15] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[16] *https://www.ncbi.nlm.nih.gov/books/NBK459126/.*

[17] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[18] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209819s001lbl.pdf.*

[19] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204442s006lbl.pdf.*

[20] *https://www.fda.gov/Drugs/NewsEvents/ucm611659.htm.*

[21] 21 U.S.C. 823(g)(2).

[22] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[23] *https://www.dea.gov/drug-scheduling.*

[24] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[25] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/017116s032lbl.pdf.*

[26] *https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone.*

[27] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021897s042lbl.pdf.*

[28] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

[29] *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.*

[30] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

[31] *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.*

[32] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021897s042lbl.pdf.*

[33] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.*

medications that are not opioid agonist and antagonist medications, including drugs and biologicals, could be developed for the treatment of OUD in the future. We would like public feedback on whether there are any drug development efforts in the pipeline that could result in medications intended for use in the treatment of OUD with a novel mechanism of action that does not involve opioid agonist and antagonist mechanisms (that is, outside of activating and/or blocking opioid receptors). We also welcome comment on how medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action, such as medications approved under section 505 of the FFDCA to treat OUD and biological products licensed under section 351 of the Public Health Service Act to treat OUD, should be considered in the context of OUD treatment services provided by OTPs, and whether CMS should use the discretion afforded under section 1861(jjj)(1)(F) of the Act to include such medications in the definition of OUD treatment services given the possibility that such medications could be approved in the future.

b. Opioid Treatment Program

Section 2005 of the SUPPORT Act also amended section 1861 of the Act by adding a new subsection (jjj)(2) to define an OTP as an entity meeting the definition of OTP in 42 CFR 8.2 or any successor regulation (that is, a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1)), that meets the additional requirements set forth in subparagraphs (A) through (D) of section 1861(jjj)(2) of the Act. Specifically that the OTP:

- Is enrolled under section 1866(j) of the Act;
- Has in effect a certification by SAMHSA for such a program;
- Is accredited by an accrediting body approved by SAMHSA; and
- Meets such additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services.

These requirements are discussed in more detail in this section.

(1) Enrollment

As discussed previously, under section 1861(jjj)(2)(A) of the Act, an OTP must be enrolled in Medicare to receive Medicare payment for covered OUD treatment services under section 1861(jjj)(1) of the Act. We refer the reader to section III.H. of this proposed rule, Medicare Enrollment of Opioid Treatment Programs, for further details on our proposed policies related to enrollment of OTPs.

(2) Certification by SAMHSA

As provided in section 1861(jjj)(2)(B) of the Act, OTPs must be certified by SAMHSA to furnish Medicare-covered OUD treatment services. SAMHSA has created a system to certify and accredit OTPs, which is governed by 42 CFR part 8, subparts B and C. This regulatory framework allows SAMHSA to focus its oversight efforts on improving treatment rather than solely ensuring that OTPs are meeting regulatory criteria, and preserves states' authority to regulate OTPs. To be certified by SAMHSA, OTPs must comply with the federal opioid treatment standards as outlined in § 8.12, be accredited by a SAMHSA-approved accreditation body, and comply with any other conditions for certification established by SAMHSA. Specifically, SAMHSA requires OTPs to provide the following services:

- *General*—OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.
- *Initial medical examination services*—OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP.
- *Special services for pregnant patients*—OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services for pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.
- *Initial and periodic assessment services*—Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment.
- *Counseling services*—OTPs must provide adequate substance abuse counseling to each patient as clinically necessary by a program counselor, qualified by education, training, or experience to assess the patient's psychological and sociological background.
- *Drug abuse testing services*—OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, defined in 42 CFR 8.2 as detoxification treatment not in excess of 30 days, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

The provisions governing recordkeeping and patient confidentiality at § 8.12(g)(1) require that OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. All records are required to be kept confidential in accordance with all applicable federal and state requirements. The requirements at § 8.12(g)(2) state that OTPs shall document in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances, which is determined by the medical director or program physician of the OTP in which the patient is enrolled (42 CFR 8.12(g)(2)). Additionally, the requirements at § 8.12(h) address medication administration, dispensing, and use.

SAMHSA requires that OTPs shall ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. OTPs shall use only those opioid agonist treatment medications that are approved by the FDA for use in the treatment of OUD. They must maintain current procedures that are adequate to ensure that the dosing requirements are met, and each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling.

At § 8.12(i), regarding unsupervised or ''take-home'' use of opioid agonist treatment medications, SAMHSA has specified that OTPs must follow requirements specified by SAMHSA to limit the potential for diversion of opioid agonist treatment medications to the illicit market when dispensed to patients as take-homes, including maintaining current procedures to identify the theft or diversion of take-

home medications. The requirements at § 8.12(j) for interim maintenance treatment, state that the program sponsor of a public or nonprofit private OTP subject to the approval of SAMHSA and the state, may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. Patients in interim maintenance treatment are permitted to receive daily dosing, but take-homes are not permitted. During interim maintenance treatment, initial treatment plans and periodic treatment plan evaluations are not required and a primary counselor is not required to be assigned to the patient. The OTP must be able to transfer these patients from interim maintenance into comprehensive maintenance treatment within 120 days. Interim maintenance treatment must be provided in a manner consistent with all applicable federal and state laws.

The SAMHSA requirements at § 8.12(b) address administrative and organizational structure, requiring that an OTP's organizational structure and facilities shall be adequate to ensure quality patient care and meet the requirements of all pertinent federal, state, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director who is a physician who is licensed to practice medicine in the jurisdiction in which the OTP is located. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in 42 CFR part 8, subpart C and any regulations regarding the use of opioid agonist treatment medications in the treatment of OUD, which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable federal, state, and local laws and regulations.

The provision governing patient admission criteria at § 8.12(e) requires that an OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual of Mental Disorders, including that the person has an OUD, and that the person has had an OUD at least 1 year before admission for treatment. If under 18 years of age, the patient is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period and have the written consent of a parent, legal guardian or responsible adult designated by the relevant state authority to be eligible for maintenance treatment.

To ensure continuous quality improvement, the requirements at § 8.12(c) state that an OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes and a current Diversion Control Plan as part of its quality assurance program.

The requirements at § 8.12(d) with respect to staff credentials, state that each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.

In addition to meeting the criteria described above, OTPs must apply to SAMHSA for certification. As part of the conditions for certification, SAMHSA specifies that OTPs shall:

- Comply with all pertinent state laws and regulations.
- Allow inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or federal governmental authority.
- Comply with the provisions of 42 CFR part 2 (regarding confidentiality of substance use disorder patient records).
- Notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.
- Comply with all regulations enforced by the DEA under 21 CFR chapter II, and be registered by the DEA before administering or dispensing opioid agonist treatment medications.
- Operate in accordance with federal opioid treatment standards and approved accreditation elements.

Furthermore, SAMHSA has issued additional guidance for OTPs that describes how programs can achieve and maintain compliance with federal regulations.[34]

[34] *https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf.*

(3) Accreditation of OTPs by a SAMHSA-Approved Accrediting Body

As provided in section 1861(jjj)(2)(C) of the Act, OTPs must be accredited by a SAMHSA-approved accrediting body in order to furnish Medicare-covered OUD treatment services. In 2001, the Department of Health and Human Services (HHS) and SAMHSA issued final regulations to establish a new oversight system for the treatment of substance use disorders with MAT (42 CFR part 8). SAMHSA-approved accrediting bodies evaluate OTPs and perform site visits to ensure SAMHSA's opioid dependency treatment standards are met. SAMHSA also requires OTPs to be accredited by a SAMHSA-approved accrediting body (42 CFR 8.11).

The SAMHSA regulations establish procedures for an entity to apply to become a SAMHSA-approved accrediting body (42 CFR 8.3). When determining whether to approve an applicant as an accreditation body, SAMHSA examines the following:

- Evidence of the nonprofit status of the applicant (that is, of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a state governmental entity or political subdivision;
- The applicant's accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the federal opioid treatment standards set forth in § 8.12;
- A detailed description of the applicant's decision-making process, including:

++ Procedures for initiating and performing onsite accreditation surveys of OTPs;

++ Procedures for assessing OTP personnel qualifications;

++ Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process;

++ Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs; for suspending or revoking an OTP's accreditation; and to ensure processing of applications for accreditation and for renewal of accreditation within a timeframe approved by SAMHSA; and;

++ A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

- Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest;

- A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;
- A description of the applicant's training policies;
- Fee schedules, with supporting cost data;
- Satisfactory assurances that the applicant will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);
- Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and
- Any other information SAMHSA may require.

SAMHSA periodically evaluates the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the federal opioid treatment standards. There are currently six SAMHSA-approved accreditation bodies.[35]

(4) Provider Agreement

Section 2005(d) of the SUPPORT Act amends section 1866(e) of the Act by adding a new paragraph (3) which includes opioid treatment programs (but only with respect to the furnishing of opioid use disorder treatment services) as a ''provider of services'' for purposes of section 1866 of the Act. All providers of services under section 1866 of the Act must enter into a provider agreement with the Secretary and comply with other requirements specified in that section. These requirements are implemented at 42 CFR part 489. Therefore, we are proposing to amend part 489 to include OTPs (but only with respect to the furnishing of opioid use disorder treatment services) as a provider. Specifically, we are proposing to add OTPs (but only with respect to the furnishing of opioid use disorder treatment services) to the list of providers in § 489.2. This addition makes clear that the other requirements specified in Section 1866, and implemented in part 489, which include the limits on charges to beneficiaries, would apply to OTPs (with respect to the furnishing of opioid use disorder treatment services). We are also proposing additional changes to make clear that certain parts of part 489, which implement statutory requirements other than section 1866 of the Act, do not apply to OTPs. For example, since we are not proposing any conditions of participation for OTPs, we are proposing to amend § 489.10(a), which states that providers specified in § 489.2 must meet conditions of participation, to add that OTPs must meet the requirements set forth in part 489 and elsewhere in that chapter. In addition, we are proposing to specify that the effective date of the provider agreement is the date on which CMS accepts a signed agreement (proposed amendment to § 489.13(a)(2)), and is not dependent on surveys or an accrediting organization's determination related to conditions of participation. Finally, as noted earlier in the preamble, OTPs are required to be certified by SAMHSA and accredited by an accrediting body approved by SAMHSA. In § 489.53, we are proposing to create a basis for termination of the provider agreement if the OTP no longer meets the requirements set forth in part 489 or elsewhere in that chapter (including if it no longer has a SAMHSA certification or accreditation by a SAMHSA-approved accrediting body). Finally, we are also proposing to revise 42 CFR part 498 to ensure that OTPs have access to the appeal process in case of an adverse determination concerning continued participation in the Medicare program. Specifically, we are amending the definition of provider in § 498.2 to include OTPs. We are continuing to review the application of the provider agreement requirements to OTPs and may make further amendments to parts 489 and 498 as necessary to ensure that the existing provider agreement regulations are applied to OTPs consistent with our proposals and Section 2005 of the SUPPORT Act.

(5) Additional Conditions

As provided in section 1861(jjj)(2)(D) of the Act, to furnish Medicare-covered OUD treatment services, OTPs must meet any additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services. The comprehensive OTP standards for certification of OTPs address the same topics as would be addressed by CMS supplier standards, such as client assessment and the services required to be provided. Furthermore, the detailed process established by SAMHSA for selecting and overseeing its accreditation organizations is similar to the accrediting organization oversight process that would typically be established by CMS. Thus, we believe the existing SAMHSA certification and accreditation requirements are both appropriate and sufficient to ensure the health and safety of individuals being furnished services by OTPs, as well as the effective and efficient furnishing of such services. We also believe that creating additional conditions at this time for participation in Medicare by OTPs could create unnecessary regulatory duplication and could be potentially burdensome for OTPs. Therefore, CMS is not proposing any additional conditions for participation in Medicare by OTPs at this time. We welcome public comments on this proposed approach, including input on whether there are any additional conditions that should be required for OTPs furnishing Medicare-covered OUD treatment services.

(6) Proposed Definition of Opioid Treatment Program

We propose to define ''opioid treatment program'' at § 410.67(b) as an entity that is an opioid treatment program as defined in 42 CFR 8.2 (or any successor regulation) and meets the applicable requirements for an OTP. We propose to codify this definition at § 410.67(b). In addition, we propose that for an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA. We are also proposing that an OTP must have a provider agreement as required by section 1866(a) of the Act. We propose to codify these requirements at § 410.67(c). We welcome public comments on the proposed definition of OTP and the proposed Medicare requirements for OTPs.

3. Proposed Bundled Payments for OUD Treatment Services

Section 1834(w) of the Act, added by section 2005 of the SUPPORT Act, directs the Secretary to pay to the OTP an amount that is equal to 100 percent of a bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care. We are proposing to establish bundled payments for OUD treatment services which, as discussed above, would include the medications approved by the FDA under section 505

[35] *https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-accrediting-bodies/approved.*

of the FFDCA for use in the treatment of OUD; the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing. In calculating the proposed bundled payments, we propose to apply separate payment methodologies for the drug component (which includes the medications approved by the FDA under section 505 of the FFDCA for use in the treatment of OUD) and the non-drug component (which includes the dispensing and administration of such medications, if applicable; substance use counseling; individual and group therapy; and toxicology testing) of the bundled payments. We propose to calculate the full bundled payment rate by combining the drug component and the non-drug components. Below, we discuss our proposals for determining the bundled payments for OUD treatment services. As part of this discussion, we address payment rates for these services under the Medicaid and TRICARE programs, duration of the episode of care for which the bundled payment is made (including partial episodes), methodology for determining bundled payment rates for the drug and non-drug components, site of service, coding and beneficiary cost sharing. We propose to codify the methodology for determining the bundled payment rates for OUD treatment services at § 410.67(d).

a. Review of Medicaid and TRICARE Programs

Section 1834(w)(2) of the Act, added by section 2005(c) of the SUPPORT Act, provides that in developing the bundled payment rates for OUD treatment services furnished by OTPs, the Secretary may consider payment rates paid to the OTPs for comparable services under the state plans under title XIX of the Act (Medicaid) or under the TRICARE program under chapter 55 of title 10 of the United States Code (U.S.C.). The payments for comparable services under TRICARE and Medicaid programs are discussed below. We understand that many private payers cover services furnished by OTPs, and welcome comment on the scope of private payer OTP coverage and the payment rates private payers have established for OTPs furnishing comparable OUD treatment services. We may consider this information as part of the development of the final bundled payment rates for OUD treatment services furnished by OTPs in the final rule.

(1) TRICARE

In the ''TRICARE: Mental Health and Substance Use Disorder Treatment'' final rule, which appeared in the September 2, 2016 **Federal Register** (81 FR 61068) (hereinafter referred to as the 2016 TRICARE final rule), the Department of Defense (DOD) finalized its methodology for determining payments for services furnished to TRICARE beneficiaries by an OTP in the regulations at 32 CFR 199.14(a)(2)(ix). The payments are also described in Chapter 7, Section 5 and Chapter 1, Section 15 of the TRICARE Reimbursement Manual 6010.61–M, April 1, 2015. As discussed in the 2016 TRICARE final rule, a number of commenters indicated that they believed the rates established by DOD are near market rates and acceptable (81 FR 61079).

In the 2016 TRICARE final rule, DOD established separate payment methodologies for treatment in OTPs based on the particular medication being administered. DOD finalized a weekly all-inclusive per diem rate for OTPs when furnishing methadone for MAT. Under 32 CFR 199.14(a)(2)(ix)(A)(3)(i), this weekly rate includes the cost of the drug and the cost of related non-drug services (that is, the costs related to the intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and supportive services), hereafter referred as the non-drug services. We note that the services included in the TRICARE weekly bundle are generally comparable to the definition of OUD treatment services in Section 2005 of the SUPPORT Act. The weekly all-inclusive per diem rate for these services was determined based on preliminary review of industry billing practices (which included Medicaid and other third-party payers) for the dispensing of methadone, including an estimated daily drug cost of $3 and a daily estimated cost of $15 for the non-drug services. These daily costs were converted to an estimated weekly per diem rate of $126 ($18 per day × 7 days) in the 2016 TRICARE final rule. Under 32 CFR 199.14(a)(2)(iv)(C)(S), this rate is updated annually by the Medicare hospital inpatient prospective payment system (IPPS) update factor. The 2019 TRICARE weekly per diem rate for methadone treatment in an OTP is $133.15.[36] Beneficiary cost-sharing consists of a flat copayment that may be applied to this weekly rate.

DOD also established payment rates for other medications used for MAT (buprenorphine and extended-release injectable naltrexone) to allow OTPs to bill for the full range of medications available. Under 32 CFR 199.14(a)(2)(ix)(A)(3)(ii), DOD established a fee-for-service payment methodology for buprenorphine and extended-release injectable naltrexone because they are more likely to be prescribed and administered in an office-based treatment setting but are still available for treatment furnished in an OTP. DOD stated in the 2016 TRICARE final rule (81 FR 61080) that treatment with buprenorphine and naltrexone is more variable in dosage and frequency than with methadone. Therefore, TRICARE pays for these medications and the accompanying non-drug services separately on a fee-for-service basis. Buprenorphine is paid based on 95 percent of average wholesale price (AWP) and the non-drug component is paid on a per visit basis at an estimated cost of $22.50 per visit. Extended-release injectable naltrexone is paid at the average sales price (ASP) plus a drug administration fee while the non-drug services are also paid at an estimated per visit cost of $22.50. DOD also reserved discretion to establish the payment methodology for new drugs and biologicals that may become available for the treatment of SUDs in OTPs.

DOD instructed that OTPs use the ''Alcohol and/or other drug use services, not otherwise specified'' H-code for billing the non-drug services when buprenorphine or naltrexone is used, and required OTPs to also include both the J-code and the National Drug Code (NDC) for the drug used, as well as the dosage and acquisition cost on the claim form.[37] Drugs listed on Medicare's Part B ASP files are paid using the ASP.[38] Drugs not appearing on the Medicare ASP file are paid at the lesser of billed charges or 95 percent of the AWP.[39] Using this methodology, TRICARE estimated a daily drug cost of $10 for buprenorphine and a monthly drug cost of $1,129 for extended-release injectable naltrexone.[40]

[36] *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/MHSUD-Facility-Rates.*

[37] 81 FR 61080.

[38] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html*; *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[39] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html*; *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[40] 81 FR 61080.

(2) Medicaid (Title XIX)

States have the flexibility to administer the Medicaid program to meet their own needs within the Medicaid program parameters set forth in federal statute and regulations. All states cover and pay for some form of medications for medication-assisted treatment of OUD under their Medicaid programs. However, as of 2018, only 42 states covered methadone for MAT for OUD under their Medicaid programs.[41] We note that section 1006(b) of the SUPPORT Act amends sections 1902 and 1905 of the Social Security Act to require that Medicaid State plans cover all drugs approved under section 505 of the FFDCA to treat OUD, including methadone, and all biological products licensed under section 351 of the Public Health Service Act to treat OUD, beginning October 1, 2020. This requirement sunsets on September 30, 2025.

In reviewing Medicaid payments for OUD treatment services furnished by OTPs in a few states, we found significant variation in the MAT coverage, OUD treatment services, and payment structure among the states. Thus, it is difficult to identify a standardized Medicaid payment amount for OTP services. A number of factors such as the unit of payment, types of services bundled within a payment code, and how MAT services are paid varied among the states. For example, for treatment of OUD using methadone for MAT, most OTPs bill under HCPCS code H0020 (Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed program)) under the Medicaid program; however, the unit of payment varies by state from daily, weekly, or monthly. For example, the unit of payment in California is daily for methadone treatment,[42] while the unit of payment in Maryland for methadone maintenance is weekly,[43] and Vermont uses a monthly unit[44] of payment of these OUD treatment items and services.

For the other MAT drugs, all states cover buprenorphine and the buprenorphine-naloxone medications;[45] however, fewer than 70 percent cover the implanted or extended-release injectable versions of buprenorphine.[46] In addition, all states cover the extended-release injectable naltrexone.[47] We also found that many states pay different rates based on the specific type of drug used for MAT.

Non-drug items and services may be included in a bundled payment with the drug or paid separately, depending on the state, and can include dosing, dispensing and administration of the drug, individual and group counseling, and toxicology testing. In some states, certain services such as assessments, individual and group counseling, and toxicology testing can be billed separately. For example, some states (such as Maryland,[48] Texas,[49] and California)[50] separately reimburse for individual and group counseling services, while other states (such as Vermont[51] and New Mexico)[52] included these services in the OUD bundled payment.

b. Aspects of the Bundle

(1) Duration of Bundle

Section 1834(w)(1) of the Act requires the Secretary to pay an OTP an amount that is equal to 100 percent of the bundled payment for OUD treatment services that are furnished by the OTP to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. We are proposing that the duration of an episode of care for OUD treatment services would be a week (that is, a contiguous 7-day period that may start on any day of the week). This is similar to the structure of the TRICARE bundled payment to OTPs for methadone, which is based on a weekly bundled rate (81 FR 61079), as well as the payments by some state Medicaid programs. Given this similarity to existing coding structures, we believe a weekly duration for an episode of care would be most familiar to OTPs and therefore the least disruptive to adopt. We welcome comments on whether we should consider a daily or monthly bundled payment. We are proposing to define an episode of care at § 410.67(b) as a 1 week (contiguous 7-day) period.

We recognize that patients receiving MAT are often on this treatment regimen for an indefinite amount of time and therefore, we are not proposing any maximum number of weeks during an overall course of treatment for OUD.

(a) Requirements for an Episode

We note that SAMHSA requires OTPs to have a treatment plan for each patient that identifies the frequency with which items and services are to be provided (§ 8.12(f)(4)). We recognize that there is a range of service intensity depending on the severity of a patient's OUD and stage of treatment and therefore, a ''full weekly bundle'' may consist of a very different frequency of services for a patient in the initial phase of treatment compared to a patient in the maintenance phase of treatment, but that we would still consider the requirements to bill for the full weekly bundle to be met if the patient is receiving the majority of the services identified in their treatment plan at that time. However, for the purposes of valuation, we assumed one substance use counseling session, one individual therapy session, and one group therapy session per week and one toxicology test per month. Given the anticipated changes in service intensity over time based on the individual patient's needs, we expect that treatment plans would be updated to reflect these changes or noted in the patient's medical record, for example, in a progress note. In cases where the OTP has furnished the majority (51 percent or more) of the services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week, we propose that it could bill for a full weekly bundle. We are proposing to codify the payment methodology for full episodes of care (as well as partial episodes of care and non-drug episodes of care, as discussed below) in § 410.67(d)(2).

(b) Partial Episode of Care

We understand that there may be instances in which a beneficiary does not receive all of the services expected in a given week due to any number of issues, including, for example, an inpatient hospitalization during which a

[41] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[42] *https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Notice_18_037_SPA_Rates_Exhibit.pdf.*

[43] *https://health.maryland.gov/bhd/Documents/Rebundling%20Initiative%209-6-16.pdf.*

[44] *http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Medicaid%20Rate%20Sheet.pdf.*

[45] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[46] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[47] *https://store.samhsa.gov/system/files/medicaidfinancingmatreport.pdf.*

[48] *https://health.maryland.gov/bhd/Documents/Rebundling%20Initiative%209-6-16.pdf.*

[49] *http://www.tmhp.com/News_Items/2018/11-Nov/11-16-18%20Substance%20Use%20Disorder%20Benefits%20to%20Change%20for%20Texas%20Medicaid%20January%201,%202019.pdf.*

[50] *https://www.dhcs.ca.gov/formsandpubs/Documents/MHSUDS%20Information%20Notices/MHSUDS_Information_Notices_2018/MHSUDS_Information_Notice_18_037_SPA_Rates_Exhibit.pdf.*

[51] *http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Medicaid%20Rate%20Sheet.pdf.*

[52] *http://www.hsd.state.nm.us/uploads/FileLinks/e7cfb008157f422597cccdc11d2034f0/MAT_Proposed_reimb_MAD_website_pdf.pdf.*

https://stre.samhsa.gov/system/files/medicaidfinancingmatreport.pdfnm.us/uploads/FileLinks/c78b68d063e04ce5adffe29376ff402e/12_10_MAT_OTC_Clinics_Supp_09062012__2_.pdf.

beneficiary would not be able to go to the OTP or inclement weather that impedes access to transportation. To provide more accurate payment to OTPs in cases where a beneficiary is not able to or chooses not to receive all items and services described in their treatment plan or the OTP is unable to furnish services, for example, in the case of a natural disaster, we are proposing to establish separate payment rates for partial episodes that correspond with each of the full weekly bundles. In cases where the OTP has furnished at least one of the items or services (for example, dispensing one day of an oral MAT medication or one counseling session or one toxicology test) but less than 51 percent of the items and services included in OUD treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week, we propose that it could bill for a partial weekly bundle. In cases in which the beneficiary does not receive a drug during the partial episode, we propose that the code describing a non-drug partial weekly bundle must be used. For example, the OTP could bill for a partial episode in instances where the OTP is transitioning the beneficiary from one OUD medication to another and therefore the beneficiary is receiving less than a week of one type of medication. In those cases, two partial episodes could be billed, one for each of the medications, or one partial episode and one full episode, if all requirements for billing are met. We intend to monitor this issue and will consider whether we would need to make changes to this policy in future rulemaking to ensure that the billing for partial episodes is not being abused. We are proposing to define a partial episode of care in § 410.67(b) and to codify the payment methodology for partial episodes in § 410.67(d). We seek comments on our proposed approach to full and partial episodes, including the threshold that should be applied to determine when an OTP may bill for the full weekly bundle versus a partial episode. We also seek comment on the minimum threshold that should be applied to determine when a partial episode could be billed (for example, at least one item or service, or an alternative threshold such as 10 or 25 percent of the items and services included in OUD treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record) over the course of a week). We also welcome feedback regarding whether any other payers of OTP services allow for billing partial bundles and what thresholds they use.

(c) Non-Drug Episode of Care

In addition to the bundled payments for full and partial episodes of care that are based on the medication administered for treatment (and include both a drug and non-drug component described in detail below), we are proposing to establish a non-drug episode of care to provide a mechanism for OTPs to bill for non-drug services, including substance use counseling, individual and group therapy, and toxicology testing that are rendered during weeks when a medication is not administered, for example, in cases where a patient is being treated with injectable buprenorphine or naltrexone on a monthly basis or has a buprenorphine implant. We are proposing to codify this non-drug episode of care at § 410.67(d).

(2) Drug and Non-Drug Components

As discussed above, in establishing the bundled payment rates, we propose to develop separate payment methodologies for the drug component and the non-drug (which includes the dispensing and administration of such medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing) components of the bundled payment. Each of these components is discussed in this section.

(a) Drug Component

As discussed previously, the cost of medications used by OTPs to treat OUD varies widely. Creating a single bundled payment rate that does not reflect the type of drug used could result in access issues for beneficiaries who might be best served by treatment using a more expensive medication. As a result, we believe that the significant variation in the cost of these drugs needs to be reflected adequately in the bundled payment rates for OTP services to avoid impairing access to appropriate care.

Section 1834(w)(2) of the Act states that the Secretary may implement the bundled payment to OTPs though one or more bundles based on a number of factors, including the type of medication provided (such as buprenorphine, methadone, extended-release injectable naltrexone, or a new innovative drug). Accordingly, consistent with the discretion afforded under section 1834(w)(2) of the Act, and after consideration of payment rates paid to OTPs for comparable services by other payers as discussed above, we propose to base the OTP bundled payment rates, in part, on the type of medication used for treatment. Specifically, we propose the following categories of bundled payments to reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD:

- Methadone (oral).
- Buprenorphine (oral).
- Buprenorphine (injection).
- Buprenorphine (implant).
- Naltrexone (injection).

In addition, we propose to create a category of bundled payment describing a drug not otherwise specified to be used for new drugs (as discussed further below). We are also proposing a non-drug bundled payment to be used when medication is not administered (as discussed further below). We believe creating these categories of bundled payments based on the drug used for treatment would strike a reasonable balance between recognizing the variable costs of these medications and the statutory requirement to make a bundled payment for OTP services. We propose to codify this policy of establishing the categories of bundled payments based on the type of opioid agonist and antagonist treatment medication in § 410.67(d)(1).

i. New Drugs

We anticipate that there may be new FDA-approved opioid agonist and antagonist treatment medications to treat OUD in the future. In the scenario where an OTP furnishes MAT using a new FDA-approved opioid agonist or antagonist medication for OUD treatment that is not specified in one of our existing codes, we propose that OTPs would bill for the episode of care using the medication not otherwise specified (NOS) code, HCPCS code GXXX9 (or GXXX19 for a partial episode). In such cases, we propose to use the typical or average maintenance dose to determine the drug cost for the new bundle. Then, we propose that pricing would be determined based on the relevant pricing methodology as described later in this section (section II.G.) of the proposed rule or invoice pricing in the event the information necessary to apply the relevant pricing methodology is not available. For example, in the case of injectable and implantable drugs, which are generally covered and paid for under Medicare Part B, we propose to use the methodology in section 1847A of the Act (which bases most payments on ASP). For oral medications, which are generally covered and paid for under Medicare Part D, we propose to use ASP-based payment when we receive manufacturer-submitted ASP data for

these drugs. In the event that we do not receive manufacturer-submitted ASP pricing data, we are considering several potential pricing mechanisms (as discussed further below) to estimate the payment amounts for oral drugs typically paid for under Medicare Part D but that would become OTP drugs paid under Part B when used as part of MAT furnished in an OTP. We are not proposing a specific pricing mechanism at this time for the situation in which we do not receive manufacturer-submitted ASP pricing data, but are requesting public comment on several potential approaches for estimating the acquisition cost and payment amounts for these drugs. We will consider the comments received in developing our final policy for determining these drug prices. If the information necessary to apply the alternative pricing methodology chosen for the oral drugs is also not available to price the new medication, we propose to use invoice pricing until either ASP pricing data or the information necessary to apply the chosen pricing methodology becomes available to price the medication. We are proposing to codify this approach for determining the amount of the bundled payment for new medications in § 410.67(d)(2).The medication NOS code would be used until CMS has the opportunity to consider through rulemaking establishing a unique bundled payment for episodes of care during which the new drug is furnished. We welcome comments on this proposed approach to the treatment of new drugs used for MAT in OTPs.

As discussed above, we also welcome comments on how new medications that may be approved by the FDA in the future for use in the treatment of OUD with a novel mechanism of action (for example, not an opioid agonist and/or antagonist), such as medications approved under section 505 of the FFDCA to treat OUD and biological products licensed under section 351 of the Public Health Service Act to treat OUD, should be considered in the context of OUD treatment services provided by OTPs. We additionally welcome comments on how such new drugs with a novel mechanism of action should be priced, and specifically whether pricing for these new non-opioid agonist and/or antagonist medications should be determined using the same pricing methodology proposed for new opioid agonist and antagonist treatment medications, described above or whether an alternative pricing methodology should be used.

(b) Non-Drug Component

i. Counseling, Therapy, Toxicology Testing, and Drug Administration

As discussed above, the bundled payment is for OUD treatment services furnished during the episode of care, which we are proposing to define as the FDA-approved opioid agonist and antagonist treatment medications, the dispensing and administration of such medications (if applicable), substance use disorder counseling by a professional to the extent authorized under state law to furnish such services, individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under state law), and toxicology testing. The non-drug component of the OUD treatment services includes all items and services furnished during an episode of care except for the medication.

Under the SAMSHA certification standards at § 8.12(f)(5), OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. We note that section 1861(jjj)(1)(C) of the Act, as added by section 2005(b) of the SUPPORT Act defines OUD treatment services as including ''substance use counseling by a professional to the extent authorized under state law to furnish such services.'' Therefore, professionals furnishing therapy or counseling services for OUD treatment must be operating within state law and scope of practice. These professionals could include licensed professional counselors, licensed clinical alcohol and drug counselors, and certified peer specialists that are permitted to furnish this type of therapy or counseling by state law and scope of practice. To the extent that the individuals furnishing therapy or counseling services are not authorized under state law to furnish such services, the therapy or counseling services would not be covered as OUD treatment services.

Additionally, under SAMSHA certification standards at § 8.12(f)(6), OTPs are required to provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. These drug abuse tests (which are identified as toxicology tests in the definition of OUD treatment services in section 1861(jjj)(1)(E) of the Act) are used for diagnosing, monitoring and evaluating progress in treatment. The testing typically includes tests for opioids and other controlled substances. Urinalysis is primarily used for this testing; however, there are other types of testing such as hair or fluid analysis that could be used. We note that any of these types of toxicology tests would be considered to be OUD treatment services and would be included in the bundled payment for services furnished by an OTP.

The non-drug component of the bundle also includes the cost of drug dispensing and/or administration, as applicable. Additional details regarding our proposed approach for pricing this aspect of the non-drug component of the bundle are included in our discussion of payment rates later in this section.

ii. Other Services

As discussed earlier, we are proposing to define OUD treatment services as those items and services that are specifically enumerated in section 1861(jjj)(1) of the Act, including services that are furnished via telecommunications technology, and are seeking comment on any other items and services we might consider including as OUD treatment services under the discretion given to the Secretary in subparagraph (F) of that section to determine other appropriate items and services. If we were to finalize a definition of OUD treatment services that includes any other items or services, such as intake activities or periodic assessments as discussed above, we would consider whether any changes to the payment rates for the bundled payments are necessary. See below for additional discussion related to how we could price these services.

(3) Adjustment to Bundled Payment Rate for Additional Counseling or Therapy Services

In addition to the items and services already included in the proposed bundles, we recognize that counseling and therapy are important components of MAT and that patients may need to receive counseling and/or therapy more frequently at certain points in their treatment. We seek to ensure that patients have access to these needed services. Accordingly, we are proposing to adjust the bundled payment rates through the use of an add-on code in order to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan. As noted previously, we understand that there is variability in the frequency of services a patient might receive in a given week depending on the patient's severity and stage of treatment; however, we assume

that a typical case might include one substance use counseling session, one individual therapy session, and one group therapy session per week. We further understand that the frequency of services will vary among patients and will change over time based on the individual patient's needs. We expect that the patient's treatment plan or the medical record will be updated to reflect when there are changes in the expected frequency of medically necessary services based on the patient's condition and following such an update, the add-on code should no longer be billed if the frequency of the patient's counseling and/or therapy services is consistent with the treatment plan or medical record. In the case of unexpected or unforeseen circumstances that are time-limited, resolve quickly, and do not lead to updates to the treatment plan, we expect that the medical necessity for billing the add-on code would be documented in the medical record. This add-on code (HCPCS code GXX19) would describe each additional 30 minutes of counseling or group or individual therapy furnished in a week of MAT, which could be billed in conjunction with the codes describing the full episode of care or the partial episodes. For example, there may be some weeks when a patient has a relapse or unexpected psychosocial stressors arise that warrant additional reasonable and necessary counseling services that were not foreseen at the time that the treatment plan was developed. Additionally, we note that there may be situations in which the add-on code could be billed in conjunction with the code for a partial episode; for example, if a patient requires prolonged counseling services on the initial day of treatment, but does not return for any of the other services specified in their treatment plan, such as daily medication dispensing, for the remainder of that week. We acknowledge that an unintended consequence of using the treatment plan is a potential incentive for OTPs to document minimal counseling and/or therapy needs for a beneficiary, thereby resulting in increased opportunity for billing the add-on code. We expect that OTPs will ensure that treatment plans reflect the full scope of services expected to be furnished during an episode of care and that they will update treatment plans regularly to reflect changes. We intend to monitor this issue and will consider whether we need to make changes to this policy through future rulemaking to ensure that this adjustment is not being abused. We welcome comments on the proposed add-on code and the threshold for billing. We propose to codify this adjustment to the bundled payment rate for additional counseling or therapy services in § 410.67(d)(3)(i).

(4) Site of Service (Telecommunications)

In recent years, we have sought to decrease barriers to access to care by furthering policies that expand the use of communication technologies. In the CY 2019 PFS final rule (83 FR 59482), we finalized new separate payments for communication technology-based services, including a virtual check-in and a remote evaluation of pre-recorded patient information. SAMHSA's federal guidelines (*https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf*) for OTPs refer to the CMS guidance on telemedicine and also state that OTPs are advised to proceed with full understanding of requirements established by state or health professional licensing boards. SAMHSA's federal guidelines for OTPs state that exceptional attention needs to be paid to data security and privacy in this evolving field. Telemedicine services should, under no circumstances, expand the scope of practice of a healthcare professional or permit practice in a jurisdiction (the location of the patient) where the provider is not licensed.

We are proposing to allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the bundle via two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries. We believe this is an appropriate approach because, as discussed previously, we expect the telehealth services that will be furnished by OTPs will be similar to the Medicare telehealth services furnished under section 1834(m) of the Act, and the use of two-way interactive audio-video communication technology is required for these Medicare telehealth services under § 410.78(a)(3). By allowing use of communication technology in furnishing these services, OTPs in rural communities or other health professional shortage areas could facilitate treatment through virtual care coming from an urban or other external site; however, we note that the physicians and other practitioners furnishing these services would be required to comply with all applicable requirements related to professional licensing and scope of practice.

We note that section 1834(m) of the Act applies only to Medicare telehealth services furnished by a physician or other practitioner. Because OUD treatment services furnished by an OTP are not considered to be services furnished by a physician or other practitioner, the restrictions of section 1834(m) of the Act would not apply. Additionally, we note that counseling or therapy furnished via communication technology as part of OUD treatment services furnished by an OTP must not be separately billed by the practitioner furnishing the counseling or therapy because these services would already be paid through the bundled payment made to the OTP.

We are proposing to include language in § 410.67(b) in the definition of opioid use disorder treatment services to allow OTPs to use two-way interactive audio-video communication technology, as clinically appropriate, in furnishing substance use counseling and individual and group therapy services, respectively. We invite comment as to whether this proposal, including whether furnishing these services through communication technology is clinically appropriate. We also invite public comment on other components of the bundle that may be clinically appropriate to be furnished via communication technology, while also considering SAMHSA's guidance that OTPs should pay exceptional attention to data security and privacy.

(5) Coding

We are proposing to adopt a coding structure for OUD treatment services that varies by the medication administered. To operationalize this approach, we are proposing to establish G codes for weekly bundles describing treatment with methadone, buprenorphine oral, buprenorphine injectable, buprenorphine implants (insertion, removal, and insertion/removal), extended-release injectable naltrexone, a non-drug bundle, and one for a medication not otherwise specified. We also propose to establish partial episode G codes to correspond with each of those bundles, respectively. Additionally, we propose to create an add-on code to describe additional counseling that is furnished beyond the amount specified in the patient's treatment plan. As discussed above, we are seeking comment on whether to include intake activities and periodic assessments in the definition of OUD treatment services. Were we to finalize including these activities in the definition of OUD treatment services, we welcome feedback on whether we should consider modifying the payment associated with the bundle or creating add-on codes for services such as the

initial physical examination, initial assessments and preparation of a treatment plan, periodic assessments or additional toxicology testing, and if so, what inputs we might consider in pricing such services, such as payment amounts for similar services under the PFS or Clinical Lab Fee Schedule (CLFS). For example, to price the initial assessment, medical examination, and development of a treatment plan, we could crosswalk to the Medicare payment rate for a level 3 Evaluation and Management (E/M) visit for a new patient and to price the periodic assessments, we could crosswalk to the Medicare payment rate for a level 3 E/M visit for an established patient. To price additional toxicology testing, we could crosswalk to the Medicare payment for presumptive drug testing, such as that described by CPT code 80305. Additionally, we welcome feedback on whether we should consider creating codes to describe bundled payments that include only the cost of the drug and drug administration as applicable in order to account for beneficiaries who are receiving interim maintenance treatment (as described previously in this section) or other situations in which the beneficiary is not receiving all of the services described in the full bundles.

Regarding the non-drug bundle, we note that this code would be billed for services furnished during an episode of care or partial episode of care when a medication is not administered. For example, when a patient receives a buprenorphine injection on a monthly basis, the OTP will only require payment for the medication during the first week of the month when the injection is given, and therefore, would bill the code describing the bundle that includes injectable buprenorphine during the first week of the month and would bill the code describing the non-drug bundle for the remaining weeks in that month for services such as substance use counseling, individual and group therapy, and toxicology testing.

As discussed previously, we propose that the codes describing the bundled payment for an episode of care with a medication not otherwise specified, HCPCS codes GXXX9 and GXX18, should be used when the OTP furnishes MAT with a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. OTPs would use these codes until we have the opportunity to propose and finalize a new G code to describe the bundled payment for treatment using that drug and price it accordingly in the next rulemaking cycle. We note that the code describing the weekly bundle for a medication not otherwise specified should not be used when the drug being administered is not a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD, and therefore, for which Medicare would not have the authority to make payment since section 1861(jjj)(1)(A) of the Act requires that the medication must be an opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. Given the program integrity concerns regarding the potential for misuse of such a code, we also welcome comments as to whether this code is needed.

The codes and long descriptors for the proposed OTP bundled services are:

- HCPCS code GXXX1: *Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX2: *Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX3: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX4: *Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX5: *Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX6: *Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX7: *Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX8: *Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXXX9: *Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).*
- HCPCS code GXX10: *Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX1.*
- HCPCS code GXX11: *Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX2.*
- HCPCS code GXX12: *Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX3.*

• HCPCS code GXX13: *Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode (only to be billed once every 6 months). Do not report with GXXX4.*

• HCPCS code GXX14: *Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX5.*

• HCPCS code GXX15: *Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX6.*

• HCPCS code GXX16: *Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX7.*

• HCPCS code GXX17: *Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX8.*

• HCPCS code GXX18: *Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX9.*

• HCPCS code GXX19: *Each additional 30 minutes of counseling or group or individual therapy in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*

See Table 15 for proposed valuations for HCPCS codes GXXX1–GXX19. We propose that only an entity enrolled with Medicare as an OTP could bill these codes. Additionally, we propose that OTPs would be limited to billing only these codes describing bundled payments, and may not bill for other codes, such as those paid under the PFS.

(6) Payment Rates

The codes describing the proposed OTP bundled services (HCPCS codes GXXX1–GXX19) would be assigned flat dollar payment amounts, which are listed in Table 15. As discussed previously, section 2005 of the SUPPORT Act amended the definition of ''medical and other health services'' in section 1861(s) of the Act to provide for coverage of OUD treatment services furnished by an OTP and also added a new section 1834(w) to the Act and amended section 1833(a)(1) of the Act to establish a bundled payment to OTPs for OUD treatment services furnished during an episode of care beginning on or after January 1, 2020. Therefore, OUD treatment services and the payments for such services are wholly separate from physicians' services, as defined under section 1848(j)(3) of the Act, and for which payment is made under the section 1848 of the Act. Because OUD treatment services are not considered physicians' services and are paid outside the PFS, they would not be priced using relative value units (RVUs).

Consistent with section 1834(w) of the Act, which requires the Secretary to make a bundled payment for OUD treatment services furnished by OTPs, we are proposing to build the payment rates for OUD treatment services by combining the cost of the drug and the non-drug components (as applicable) into a single bundled payment as described in more detail below.

(a) Drug Component

As part of determining a payment rate for these proposed bundles for OUD treatment services, a dosage of the applicable medication must be selected in order to calculate the costs of the drug component of the bundle. We propose to use the typical or average maintenance dose, as discussed earlier in this section, to determine the drug costs for each of the proposed bundles. As dosing for some, but not all, of these drugs varies considerably, this approach attempts to strike an appropriate balance between high- and low-dose drug regimens in the context of a bundled payment. Specifically, we propose to calculate payment rates using a 100 mg daily dose for methadone, a 10 mg daily dose for oral buprenorphine, a 100 mg monthly dose for the extended-release buprenorphine injection, four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and a 380 mg monthly dose for extended-release injectable naltrexone. We invite public comments on our proposal to use the typical maintenance dose in order to calculate the drug component of the bundled payment rate for each of the proposed codes. We also seek comment on the specific typical maintenance dosage level that we have identified for each drug, and a process for identifying the typical maintenance dose for new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA when such medications are billed using the medication NOS code, such as using the FDA-approved prescribing information or a review of the published, preferably peer-reviewed, literature. We note that the bundled payment rates are intended to be comprehensive with respect to the drugs provided; therefore, we do not intend to include any other amounts related to drugs, other than for administration, as discussed below. This means, for example, that we would not pay for drug wastage, which we do not anticipate to be significant in the OTP setting.

i. Potential Drug Pricing Data Sources

Payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. We are proposing to estimate an OTP's costs for the drug component of the bundles based on available data regarding drug costs rather than a provider-specific cost-to-charge ratio or another more direct assessment of facility or industry-specific drug costs. OTPs do not currently report costs associated with their services to the Medicare program, and we do not believe that a cost-to-charge ratio based on such reported information could be available for a significant period of time. Furthermore, we are unaware of any industry-specific data that may be used to more accurately assess the prices at which OTPs acquire the medications used for OUD treatment. Therefore, at this time, we are proposing to estimate an OTP's costs for the drugs used in MAT based on other available data sources, rather than applying a cost-to-charge ratio or

another more direct assessment of drug acquisition cost, though we intend to continue to explore alternate ways to gather this information. As described in greater detail below, we propose that the payment amounts for the drug component of the bundles be based on CMS pricing mechanisms currently in place. We request comment on other potential data sources for pricing OUD treatment medications either generally or specifically with respect to acquisition by OTPs. In the case of oral drugs that we are proposing to include in the OTP bundled payments and for which we do not receive manufacturer-submitted ASP data, we are considering several potential approaches for determining the payment amounts for the drug component of the bundles. Although we are not proposing a specific pricing mechanism at this time, we are soliciting comments on several different approaches, and we intend to develop a final policy for determining the payment amount for the drug component of the relevant bundles after considering the comments received.

In considering the payment amount for the drug component of each of the bundled payments that include a drug, we will begin by breaking the drugs into two categories based on their current coverage and payment by Medicare. First, we discuss the injectable and implantable drugs, which are generally covered and paid for under Medicare Part B, and then discuss the oral medications, which are generally covered and paid for under Medicare Part D.[53] Buprenorphine (injection), buprenorphine (implant), and naltrexone (injection) would fall into the former category and methadone and buprenorphine (oral) would fall into the latter category.

ii. Part B Drugs

Part B includes a limited drug benefit that encompasses drugs and biologicals described in section 1861(t) of the Act. Currently, covered Part B drugs fall into three general categories: Drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment, and other drugs specified by statute (generally in section 1861(s)(2) of the Act). Types of providers and suppliers that are paid for all or some of the Medicare-covered Part B drugs that they furnish include physicians, pharmacies, durable medical equipment suppliers, hospital outpatient departments, and end-stage renal disease (ESRD) facilities.

The majority of Part B drug expenditures are for drugs furnished incident to a physician's service. Drugs furnished incident to a physician's service are typically injectable drugs that are administered in a non-facility setting (covered under section 1861(s)(2)(A) of the Act) or in a hospital outpatient setting (covered under section 1861(s)(2)(B) of the Act). The statute (sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act) limits ''incident to'' services to drugs that are not usually self-administered; self-administered drugs, such as orally administered tablets and capsules are not paid for under the ''incident to'' provision. Payment for drugs furnished incident to a physician's service falls under section 1842(o) of the Act. In accordance with section 1842(o)(1)(C) of the Act, ''incident to'' drugs furnished in a non-facility setting are paid under the methodology in section 1847A of the Act. ''Incident to'' drugs furnished in a facility setting also are paid using the methodology in section 1847A of the Act when it has been incorporated under the relevant payment system (for example, the Hospital Outpatient Prospective Payment System (OPPS) [54]).

In most cases, determining payment using the methodology in section 1847A of the Act means payment is based on the ASP plus a statutorily mandated 6 percent add-on. The payment for these drugs does not include costs for administering the drug to the patient (for example, by injection or infusion); payments for these physician and hospital services are made separately, and the payment amounts are determined under the PFS [55] and the OPPS, respectively. The ASP payment amount determined under section 1847A of the Act reflects a volume-weighted ASP for all NDCs that are assigned to a HCPCS code. The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act such as sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and price concessions reflected in the manufacturer's determination of ASP.

Although the Part B drug benefit is generally considered to be limited in scope, it includes many categories of drugs and encompasses a variety of care settings and payment methodologies. In addition to the ''incident to'' drugs described above, Part B also covers and pays for certain oral drugs with specific benefit categories defined under section 1861(s) of the Act including certain oral anti-cancer drugs and certain oral antiemetic drugs. In accordance with section 1842(o)(1) of the Act or through incorporation under the relevant payment system as discussed above, most of these oral Part B drugs are also paid based on the ASP methodology described in section 1847A of the Act.

However, at times Part B drugs are paid based on wholesale acquisition cost (WAC) as authorized under section 1847A(c)(4) of the Act [56] or average manufacturer price (AMP)-based price substitutions as authorized under section 1847A(d) of the Act.[57] Also, in accordance with section 1842(o) of the Act, other payment methodologies may be applied to determine the payment amount for certain Part B drugs, for example, AWP-based payments (using current AWP) are made for influenza, pneumococcal pneumonia, and hepatitis B vaccines.[58] We also use current AWP to make payment under the OPPS for very new drugs without an ASP.[59] Contractors may also make independent payment amount determinations in situations where a national price is not available for physician and other supplier claims and for drugs that are specifically excluded from payment based on section 1847A of the Act (for example, radiopharmaceuticals as noted in section 303(h) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003). In such cases, pricing may be determined based on compendia or invoices.[60]

While most Part B drugs are paid based on the ASP methodology, MedPAC has noted that the ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue

[53] Because, by law, methadone used in MAT cannot be dispensed by a pharmacy, it is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug and can be dispensed by a pharmacy.

[54] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

[55] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

[56] See 75 FR 73465–73466, the section titled Partial Quarter ASP data.

[57] See 77 FR 69140.

[58] Section 1842(o)(1)(A)(iv) of the Act.

[59] 80 FR 70426 and 80 FR 70442–3; Medicare Claims Processing Manual 100–04, Chapter 17, Section 20.1.3.

[60] Medicare Claims Processing Manual 100–04, Chapter 17, Section 20.1.3.

for more expensive drugs.[61] The ASP payment amount also does not vary based on the price an individual provider or supplier pays to acquire the drug. The statute does not identify a reason for the additional 6 percent add-on above ASP; however, as noted in the MedPAC report (and by sources cited in the report), the add-on is needed to account for handling and overhead costs and/or for additional mark-up in the distribution channels that are not captured in the manufacturer-reported ASP.[62]

We propose to use the methodology in section 1847A of the Act (which bases most payments on ASP) to set the payment rates for the ''incident to'' drugs. However, we propose to limit the payment amounts for ''incident to'' drugs to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code. We believe limiting the add-on will incentivize the use of the most clinically appropriate drug for a given patient. In addition, we understand that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels. We also propose to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs. Please note that the quarterly ASP Drug Pricing Files include ASP plus 6 percent payment amounts.[63] Accordingly, we would adjust these amounts consistent with our proposal to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a HCPCS code. Proposed payment rates are provided below in this section of this proposed rule. A discussion of the proposed annual payment update methodology is also provided below. We propose to codify the ASP payment methodology for the drug component at § 410.67(d)(2). We solicit public comment on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP payment rates.

iii. Oral Drugs

We propose to use ASP-based payment, which would be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart 800, to set the payment rates for the oral product categories when we receive manufacturer-submitted ASP data for these drugs. We believe that using the ASP pricing data for oral OTP drugs currently covered under Part D[64] would facilitate the computation of the estimated costs of these drugs. However, we do not collect ASP pricing information under section 1927(b) of the Act for these drugs. We request public comment on whether manufacturers would be willing to submit ASP pricing data for OTP drugs currently covered under Part D on a voluntary basis.

We also propose to limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code. We believe limiting the add-on will incentivize the use of the most clinically appropriate drug for a given patient. In addition, we understand that many OTPs purchase directly from drug manufacturers, thereby limiting the markup from distribution channels. We propose to use the same version of the quarterly manufacturer-submitted data used for calculating the most recently posted ASP data files in preparing the CY 2020 payment rates for OTPs. Please note that the quarterly ASP Drug Pricing Files include ASP plus 6 percent payment amounts.[65] Accordingly, we would adjust these amounts consistent with our proposal to limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a HCPCS code. Proposed payment rates are provided below in this section of this proposed rule. A discussion of the proposed annual payment update methodology is also provided below. We propose to codify the ASP payment methodology for the drug component at § 410.67(d)(2). We solicit public comment on these proposals, as well as on using alternative ASP-based payments to price these drugs, such as a rolling average of the past year's ASP payment rates.

In the event that we do not receive manufacturer-submitted ASP pricing data, we are considering several potential pricing mechanisms to estimate the payment amounts for oral drugs typically paid for under Medicare Part D but that would become OTP drugs paid under Part B when used as part of MAT in an OTP. We are not proposing a specific pricing mechanism for these drugs at this time, but are requesting public comment on the following potential approaches for estimating the acquisition cost and payment amounts for these drugs and on alternative approaches. We will consider the comments received in developing our final policy for determining these drug prices.

Approach 1: The Methodology in Section 1847A of the Act

One approach for estimating the cost of the drugs that are currently covered under Part D and for which ASP data are not available would be to use the methodology in section 1847A of the Act. Please see above for a discussion of the methodology in section 1847A of the Act. Under the methodology in section 1847A of the Act, when ASP data are not available, this option would price drugs using, for example, WAC or invoice pricing.

Approach 2: Medicare's Part D Prescription Drug Plan Finder Data

On January 28, 2005, we issued the ''Medicare Program; Medicare Prescription Drug Benefit'' final rule (70 FR 4194) which implemented the Medicare voluntary prescription drug benefit, as enacted by section 101 of the MMA. Beginning on January 1, 2006, a prescription drug benefit program was available to beneficiaries with much broader drug coverage than was previously provided under Part B to include: Brand-name prescription drugs and biologicals, generic drugs, biosimilars, vaccines, and medical supplies associated with the injection of insulin.[66] This prescription drug benefit is offered to Medicare beneficiaries through Medicare Advantage Drug Plans (MA–PDs) and stand-alone Prescription Drug Plans (PDPs). The prescription drug benefit under Medicare Part D is administered based on the ''negotiated prices'' of covered Part D drugs. Under § 423.100 of the Part D regulations, the negotiated price of a Part D drug equals the amount paid by the Part D sponsor (or its pharmacy benefit manager) to the pharmacy at the point-of-sale for that drug. Typically, these Part D ''negotiated prices'' are based on AWP minus a percentage for brand drugs or either the maximum allowable cost, which is based on proprietary methodologies used to establish the same payment for therapeutically equivalent products marketed by multiple labelers with different AWPs,

[61] See MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65–72.

[62] Ibid.

[63] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html.*

[64] Please note that methadone is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug.

[65] See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html.*

[66] See section 1860D–2(e) of the Act.

or the Generic Effective Rate, which guarantees aggregate minimum reimbursement (for example, AWP–85 percent). The negotiated price under Part D also includes a dispensing fee (for example, $1–$2), which is added to the cost of the drug.

Many of the beneficiaries who choose to enroll in Part D drug plans must pay premiums, deductibles, and copayments/co-insurance. The Medicare Prescription Drug Plan Finder is an online tool available at *http://www.medicare.gov*. This web tool allows beneficiaries to make informed choices about enrolling in Part D plans by comparing the plans' benefit packages, premiums, formularies, pharmacies, and pricing data. PDPs and MA–PDs are required to submit this information to CMS for posting on the Medicare Drug Plan Finder. The database structure provides the drug pricing and pharmacy network information necessary to accurately communicate plan information in a comparative format. The Medicare Prescription Drug Plan Finder displays information on pharmacies that are contracted to participate in the sponsors' network as either retail or mail order pharmacies.

Another approach for estimating the cost of the drugs that are currently covered under Part D and for which ASP data are not available would be to use data retrieved from the online Medicare Prescription Drug Plan Finder. For example, the Part D drug prices for each drug used by an OTP as part of MAT could be estimated based on a national average price charged by all Part D plans and their network pharmacies. However, the prices listed in the Medicare Prescription Drug Plan Finder generally reflect the prices that are negotiated by larger buying groups, as larger pharmacies often have significant buying power and smaller pharmacies generally contract with a pharmacy services administrative organization (PSAO). As a result, our primary concern with this pricing approach is that such prices may fail to reflect the drug prices that smaller OTP facilities may pay in acquiring these drugs and could therefore disadvantage these facilities. If we were to select this pricing approach for oral drugs for which ASP data are not available, we would anticipate setting the pricing for these drugs using the most recent Medicare Drug Plan Finder data available at the drafting of the CY 2020 PFS final rule. We note that, for the Part B ESRD prospective payment system (PPS) outlier calculation, which provides ESRD facilities with additional payment in situations where the costs for treating patients exceed an established threshold under the ESRD PPS, we chose to adopt the ASP methodology in section 1847A of the Act, and the other pricing methodologies under section 1847A of the Act, as appropriate, when ASP data are not available, to price the renal dialysis drugs and biological products that were or would have been separately billable under Part B prior to implementation of the ESRD PPS,[67] and the national average drug prices based on the Medicare Prescription Drug Plan Finder as the data source for pricing the renal dialysis drugs or biological products that were or would have been separately covered under Part D prior to implementation of the ESRD PPS.[68]

We believe that all of the MAT drugs proposed for inclusion in the OTP benefit that are currently covered under Part D have clinical treatment indications beyond MAT such as for the treatment of pain.[69] These drugs will continue to be covered under Part D for these other indications. Buprenorphine will continue to be covered under Part D for MAT as well. Consequently, Part D pricing information should continue to be available for these drugs and could be used in the computation of payment under the approach discussed above.

Because, by law, methadone used in MAT cannot be dispensed by a pharmacy, it is not currently considered a Part D drug when used for MAT. Methadone used for this purpose can be dispensed only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug and can be dispensed by a pharmacy. Accordingly, we also seek comment on the applicability of Part D payment rates for methadone dispensed by a pharmacy to methadone dispensed by an OTP for MAT.

Approach 3: Wholesale Acquisition Cost (WAC)

Another approach for estimating the cost of the oral drugs that we propose to include as part of the bundled payments but for which ASP data are not available would be to use WAC. Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the U.S., not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data. As noted above in the discussion of Part B drugs, WAC is used as the basis for pricing some Part B drugs; for example, it is used when it is less than ASP in the case of single source drugs (section 1847A(b)(4) of the Act) and in cases where ASP is unavailable during the first quarter of sales (section 1847A(c)(4) of the Act).

Because WAC is the manufacturer's list price to wholesalers, we believe that it is more reflective of the price paid by the end user than the AWP. As a result, we believe that this pricing mechanism would be consistent with pricing that currently occurs for drugs that are separately billable under Part B. However, we have concerns about the fact that WAC does not include prompt pay or other discounts, rebates, or reductions in price. If we select this option to estimate the cost of certain drugs, we would develop pricing using the most recent data files available at the drafting of the CY 2020 PFS final rule.

Approach 4: National Average Drug Acquisition Cost (NADAC)

Another approach for estimating the cost of the oral drugs that we propose to include as part of the bundled payments but for which ASP data are not available would be to use Medicaid's NADAC survey. This survey provides another national drug pricing benchmark. CMS conducts surveys of retail community pharmacy prices, including drug ingredient costs, to develop the NADAC pricing benchmark. The NADAC was designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs and is available for consideration by states to assist with their individual pharmacy payment policies.

State Medicaid agencies reimburse pharmacy providers for prescribed covered outpatient drugs dispensed to Medicaid beneficiaries. The reimbursement formula consists of two parts: (1) Drug ingredient costs; and (2) a professional dispensing fee. In a final rule with comment period titled ''Medicaid Program; Covered Outpatient Drugs,'' which appeared in the February 1, 2016 **Federal Register** (81 FR 5169), we revised the methodology that state Medicaid programs use to determine drug ingredient costs, establishing an Actual Acquisition Cost (AAC) based determination, as opposed to a determination based on estimated acquisition costs (EAC). AAC is defined

[67] 82 FR 50742 through 50745.

[68] 75 FR 49142.

[69] For example, while methadone is not covered by Medicare Part D for MAT, methadone dispensed for pain may be considered a Part D drug.

at 42 CFR 447.502 as the agency's determination of the pharmacy providers' actual prices paid to acquire drugs marketed or sold by specific manufacturers. As explained in the Covered Outpatient Drugs final rule with comment period (81 FR 5175), CMS believes shifting from an EAC to an AAC based determination of ingredient costs is more consistent with the dictates of section 1902(a)(30)(A) of the Act. In 2010, a working group within the National Association of State Medicaid Directors (NASMD) recommended the establishment of a single national pricing benchmark based on average drug acquisition costs. Pricing metrics based on actual drug purchase prices provide greater accuracy and transparency in how drug prices are established and are more resistant to manipulation. The NASMD requested that CMS coordinate, develop, and support this benchmark.

Section 1927(f) of the Act provides, in part, that CMS may contract with a vendor to conduct monthly surveys with respect to prices for covered outpatient drugs dispensed by retail community pharmacies. We entered into a contract with Myers & Stauffer, LLC to perform a monthly nationwide retail price survey of retail community pharmacy covered outpatient drug prices (CMS–10241, OMB 0938–1041) and to provide states with weekly updates on pricing files, that is, the NADAC files. The NADAC survey process focuses on drug ingredient costs for retail community pharmacies. The survey collects acquisition costs for covered outpatient drugs purchased by retail pharmacies, which include invoice prices from independent and chain retail community pharmacies. The survey data provide information that CMS uses to assure compliance with federal requirements. We believe NADAC data could be used to set the prices for the oral drugs furnished by OTPs for which ASP data are not available. Survey data on invoice prices provide the closest pricing metric to ASP that we are aware of. However, similar to the other available pricing metrics, we have concerns about the applicability of retail pharmacy prices to the acquisition costs available to OTPs since we have no evidence to suggest that these entities would be able to acquire drugs at a similar price point. If we select this option, we would develop pricing using the most recent data files available at the drafting of the CY 2020 PFS final rule.

Alternative Methadone Pricing: TRICARE

We are also considering an approach for estimating the cost of methadone using the amount calculated by TRICARE. As discussed above in this section of this proposed rule, the TRICARE rates for medications used in OTPs to treat opioid use disorder are spelled out in the 2016 TRICARE final rule (81 FR 61068); in the regulations at § 199.14(a)(2)(ix); and in Chapter 7, Section 5 and Chapter 1, Section 15 of the TRICARE Reimbursement Manual 6010.61–M, April 1, 2015.

In the 2016 TRICARE final rule, DOD established separate payment methodologies for OTPs based on the particular medication being administered for treatment.[70] Based on TRICARE's review of industry billing practices, the initial weekly bundled rate for administration of methadone included a daily drug cost of $3, which is subject to an update factor.[71]

This option would only be applicable for methadone because TRICARE has developed a fee-for-service payment methodology for buprenorphine and naltrexone.[72] In the 2016 TRICARE final rule, the DOD stated that the payments for buprenorphine and naltrexone are more variable in dosage and frequency for both the drug and non-drug services.[73] Accordingly, TRICARE pays for drugs listed on Medicare's Part B ASP files, such as the injectable and implantable versions of buprenorphine using the ASP; drugs not appearing on the Medicare ASP file, such as oral buprenorphine, are priced at the lesser of billed charges or 95 percent of the AWP.[74]

We believe that pricing methadone consistent with the TRICARE payment rate may provide a reasonable payment amount for methadone when ASP data are not available. As DOD noted in the 2016 TRICARE final rule, ''a number of commenters indicated that they believed the rates DOD proposed for OTPs' services are near market rates and are acceptable.'' [75]

We are proposing to codify this proposal to apply an alternative approach for determining the payment rate for oral drugs only if ASP data are not available in § 410.67(d)(2). We request public comment on the potential alternative approaches set forth above for estimating the cost of oral drugs that we propose to include as part of the bundled payments but for which ASP data are not available, including any other alternate sources of data to estimate the cost of these oral MAT drugs. Payment rates based on these different options are set forth in Table 14. We will consider the comments received on these different potential approaches when deciding on the approach that we will use to determine the payment rates for these drugs in the CY 2020 PFS final rule. We also invite public comment on any other potential data sources for estimating the provider acquisition costs of OTP drugs currently paid under either Part B or Part D. As noted previously, we welcome comments on how new drugs with a novel mechanism of action should be priced, and specifically whether pricing for non-opioid agonist and/or antagonist medications should be determined using the same pricing methodology, including the alternatives discussed above, as would be used for medications included in the proposed definition of OUD treatment services.

TABLE 14—ESTIMATED * INITIAL DRUG PAYMENT RATES FOR EACH PRICING APPROACH

Pricing approach (or alternative)	Estimated initial weekly drug payment for methadone	Estimated initial weekly drug payment for oral buprenorphine
Proposal: ASP-Based Payment	ASPs currently not reported	ASPs currently not reported.
Approach 1: The Methodology in Section 1847A of the Act.	$29.61	$117.68.
Approach 2: Medicare's Part D Prescription Drug Plan Finder Data.	22.47	97.65.
Approach 3: WAC	27.93	111.02.
Approach 4: NADAC	11.76	97.02.

[70] 81 FR 61079.

[71] 81 FR 61079.

[72] 81 FR 61080.

[73] 81 FR 61080.

[74] *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/C7S5.html*; *https://manuals.health.mil/pages/DisplayManualHtmlFile/TR15/30/AsOf/TR15/c1s15.html2FM10546.*

[75] 81 FR 61080.

TABLE 14—ESTIMATED * INITIAL DRUG PAYMENT RATES FOR EACH PRICING APPROACH—Continued

Pricing approach (or alternative)	Estimated initial weekly drug payment for methadone	Estimated initial weekly drug payment for oral buprenorphine
Alternative Methadone Pricing: TRICARE	22.19	N/A.

* The estimated payment amounts in this table are based on data files posted at the time of the drafting of this proposed rule. We would develop the final pricing for CY 2020 using the most recent data files available at the drafting of the CY 2020 PFS final rule.

(b) Non-Drug Component

To price the non-drug component of the bundled payments, we are proposing to use a crosswalk to the non-drug component of the TRICARE weekly bundled rate for services furnished when a patient is prescribed methadone. As described above, in 2016, TRICARE finalized a weekly bundled rate for administration of methadone that included a daily drug cost of $3, along with a $15 per day cost for non-drug services (that is, the costs related to the intake/assessment, drug dispensing and screening and integrated psychosocial and medical treatment and supportive services). The daily projected per diem cost ($18/day) was converted to a weekly rate of $126 ($18/day × 7 days) (81 FR 61079). TRICARE updates the weekly bundled methadone rate for OTPs annually using the Medicare update factor used for other mental health care services rendered (that is, the Inpatient Prospective Payment System update factor) under TRICARE (81 FR 61079). The updated amount for CY 2019 to $133.15 (of which $22.19 is the methadone cost and the remainder, $110.96, is for the non-drug services).[76] We believe using the TRICARE weekly bundled rate is a reasonable approach to setting the payment rate for the non-drug component of the bundled payments to OTPs, particularly given the time constraints in developing a payment methodology prior to the January 1, 2020 effective date of this new Medicare benefit category. The TRICARE rate is an established national payment rate that was established through notice and comment rulemaking. As a result, OTPs and other interested parties had an opportunity to present information regarding the costs of these services. Furthermore the TRICARE rate describes a generally similar bundle of services to those services that are included in the definition of OUD treatment services in section 1861(jjj)(1) of the Act. We recognize that there are differences in the patient population for TRICARE compared with the Medicare beneficiary population. However, as OTP services have not previously been covered by Medicare, it is not clear what impact, if any, these differences would have on the cost of the services included in the non-drug component of the proposed bundled payments. We are proposing to codify the methodology for determining the payment rate for the non-drug component of the bundled payments using the TRICARE weekly rate for non-drug services at § 410.67(d)(2). As part of this proposal, we would plan to monitor utilization of non-drug services by Medicare beneficiaries and, if needed, would consider in future rulemaking ways we could tailor the TRICARE payment rate for these non-drug services to the Medicare population, including dually eligible beneficiaries.

Because the TRICARE payment rate for the non-drug services included in its weekly bundled rate for methadone includes daily administration of methadone, as part of our proposed approach we would adjust the TRICARE payment rate for non-drug services for most of the other bundled payments to more accurately reflect the cost of administering the other drugs used in MAT. For the oral buprenorphine bundled payment, we propose to retain the same amount as the rate for the methadone bundled payment based on an assumption that this drug is also being dispensed daily. We understand that patients who have stabilized may be given 7–14 day supplies of oral buprenorphine at a time, but for the purposes of developing the proposed rates, we valued this service to include daily drug dispensing to account for cases where daily drug dispensing is occurring. For the injectable drugs (buprenorphine and naltrexone), we propose to subtract from the non-drug component, an amount that is comparable to the dispensing fees paid by several state Medicaid programs ($10.50) for a week of daily dispensing of methadone. This adjustment accounts for the fact that these injectable drugs are not oral drugs that are dispensed daily; we would then instead add the fee that Medicare pays for the administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372). We propose to update the amount of this adjustment annually using the same methodology that we are proposing to use to update the non-drug component of the bundled payments.

Similarly, the payment rates for the non-drug component of the codes for the weekly bundled payments for buprenorphine implants would be adjusted to add an amount for insertion and/or removal based on a direct crosswalk to the non-facility payment rates under the Medicare PFS for the insertion, removal, or insertion and removal of these implants, which describe the physician work, practice expense (PE), and malpractice costs associated with these procedures, and to remove the costs of daily drug dispensing (determined based on the dispensing fees paid by several state Medicaid programs for a week of daily dispensing of methadone, currently $10.50). For HCPCS code GXXX5, we would use a crosswalk to the rate for HCPCS code G0516 (*Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)*); for HCPCS code GXXX6, we would use a crosswalk to the rate for HCPCS code G0517 (*Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*); and for HCPCS code GXXX7, we would use a crosswalk to the rate for HCPCS code G0518 (*Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)*). The amounts for HCPCS codes G0516, G0517 and G0518 under the CY 2019 non-facility Medicare payment rate are $111.00, $126.86, and $204.70, respectively.

In order to determine the payment rates for the code describing a non-drug bundled payment, HCPCS code GXXX8, we propose to use a crosswalk to the reimbursement rate for the non-drug services included in the TRICARE weekly bundled rate for administration of methadone, adjusted to subtract the cost of methadone dispensing (using an amount that is comparable to the dispensing fees paid by several state Medicaid programs for a week of daily dispensing of methadone, which is currently $10.50).

We propose that the payment rate for the add-on code, HCPCS code GXX19, would be based on 30 minutes of

[76] *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/MHSUD-Facility-Rates.*

substance use counseling and valued based on a crosswalk to the rates set by state Medicaid programs for similar services.

i. Medication Not Otherwise Specified

We would expect the non-drug component for medication not otherwise specified bundled payments (HCPCS code GXXX9) to be consistent with the pricing methodology for the other bundled payments and therefore, be based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees. For example, for oral medications, we would use the rate for the non-drug services included in the TRICARE methadone bundle, based on an assumption that the drug is also being dispensed daily. For the injectable medications, we would adjust the TRICARE payment rate for non-drug services using the same methodology we are proposing for injectable medications above (to subtract an amount for daily dispensing and add the non-facility Medicare payment rate for administration of the injection). For implantable medications, we would also use the same methodology we propose above, with the same crosswalked non-facility Medicare payment rates (for insertion, removal, and insertion and removal). We welcome comments on all of the proposed pricing methodologies described in this section. As noted above, we also welcome comments on how new drugs with a novel mechanism of action (that is, drugs that are not opioid agonists and/or antagonists) should be priced. We additionally welcome comments on how the price of the non-drug component of such bundled payments should be determined, in particular the dispensing and/or administration fees, including whether the methodology we propose above for determining the payment rate for the non-drug component of an episodes of are that includes a new opioid agonist and antagonist medication (which is based on whether the drug is oral, injectable, or implantable) would be appropriate to use for these new drugs.

(c) Partial Episode of Care

For HCPCS codes GXX10 and GXX11 (codes describing partial episodes for methadone and oral buprenorphine), we propose that the payment rates for the non-drug component would be calculated by taking one half of the payment rate for the non-drug component for the corresponding weekly bundles. We chose one half as the best approximation of the median cost of the services furnished during a partial episode consistent with our proposal above to make a partial episode bundled payment when the majority of services described in a beneficiary's treatment plan are not furnished during a specific episode of care. However, we welcome comment on other methods that could be used to calculate these payment rates. We propose that the payment rates for the drug component of these partial episode bundles would be calculated by taking one half of the payment rate for the drug component of the corresponding weekly bundles.

For HCPCS codes GXX12 and GXX16 (codes describing partial episodes for injectable buprenorphine and naltrexone), we propose that the payment rates for the drug component would be the same as the payment rate for the drug component of the full weekly bundle so that the OTP would be reimbursed for the cost of the drug that is given at the start of the episode. For the non-drug component, we propose that the payment rate would be calculated as follows: The TRICARE non-drug component payment rate ($110.96), adjusted to remove the cost of daily administration of an oral drug ($10.50), then divided by two; that amount would be added to the fee that Medicare pays for the administration of an injection (which is currently $16.94 under the CY 2019 non-facility Medicare payment rate for CPT code 96372).

For HCPCS codes GXX13, GXX14, GXX15 (codes describing partial episodes for the buprenorphine implant insertion, removal, and insertion and removal, respectively) we propose that the payment rates for drug component would be the same as the payment rate for the corresponding weekly bundle. For the non-drug component, we propose that the payment rate would be calculated as follows: The TRICARE non-drug component payment rate ($110.96), adjusted to remove the cost of daily administration of an oral drug ($10.50), then divided by two; that amount would be added to the Medicare non-facility payment rate for the insertion, removal, or insertion and removal of the implants, respectively (based on the non-facility rates for HCPCS codes G0516, G0517, and G0518, which are currently $111.00, $126.86, and $204.70, respectively).

For HCPCS code GXX17 (code describing a non-drug partial episode of care), we propose that the payment rate would be calculated by taking one half of the payment rate for the corresponding weekly bundle.

We propose that the payment rate for the code describing partial episodes for a medication not otherwise specified (HCPCS code GXX18) would be calculated based on whether the medication is oral, injectable or implantable, following the methodology described above. For oral drugs, we would follow the methodology described for HCPCS codes GXX10 and GXX11. For injectable drugs, we would follow the methodology described for HCPCS codes GXX12 and GXX16. For implantable drugs, we would follow the methodology described for HCPCS codes GXX13, GXX14, and GXX15. We welcome comments on how partial episodes of care using new drugs with a novel mechanism of action (that is, non-opioid agonist and/or antagonist treatment medications) should be priced. For example, we could use the same approach described previously for pricing new opioid agonist and antagonist medications not otherwise specified, which is to follow the methodology based on whether the drug is oral, injectable or implantable.

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TABLE 15: OTP Code Descriptors and Proposed Approximate Payment Amounts

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
	Full weeks			
GXXX1	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$22.19	$110.96	$133.15
GXXX2	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$97.02	$110.96	$207.98
GXXX3	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,580.00	$117.40	$1,697.40
GXXX4	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,792.10	$211.46	$5,003.56
GXXX5	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$0	$227.32	$227.32
GXXX6	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$4,792.10	$305.16	$5,097.26
GXXX7	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	$1,164.38	$117.40	$1,281.78
GXXX8	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	N/A	$100.46	$100.46
GXXX9	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	-	-	-
	Partial episodes			
GXX10	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX1.*	$11.10	$55.48	$66.58

HCPCS	Descriptor	Drug Component Payment Amount**	Non-Drug Component Payment Amount***	Total Payment Amount
GXX11	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX2.*	$48.51	$55.48	$103.99
GXX12	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX3.*	$1,580.00	$67.17	$1,647.17 *
GXX13	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode (only to be billed once every 6 months). *Do not report with GXXX4.*	$4,792.10	$161.23	$4,953.33 *
GXX14	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX5.*	$0	$177.09	$177.09*
GXX15	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX6.*	$4,792.10	$254.93	$5,047.03 *
GXX16	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX7.*	$1,164.38	$67.17	$1,231.55 *
GXX17	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. *Do not report with GXXX8.*	N/A	$50.23	$50.23
GXX18	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode. Do not report with GXXX9.	-	-	-
Intensity Add-on code				
GXX19	Each additional 30 minutes of counseling or therapy in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	N/A	$26.60	$26.60

* Full drug cost and administration/dispensing fee included.

** Drug pricing subject to change pending additional data. Methadone drug costs are calculated here using TRICARE rates, oral buprenorphine drug costs are calculated here using NADAC data, and the other drug costs are calculated using the ASP data. The estimated payment amounts in this table are based on data files posted at the time of the drafting of this proposed rule. We would develop the final pricing for CY 2020 using the most recent data files available at the drafting of the CY 2020 PFS final rule.

*** The non-drug component of the methadone bundled payment rate (HCPCS code GXXX1) is $110.96 (crosswalked from the TRICARE CY 2019 rate for non-drug services, which is the weekly rate of $133.15 minus the drug cost of $22.19); the non-drug component of the oral buprenorphine bundled payment rate (HCPCS code GXXX2) is also $110.96 (crosswalked from the non-drug component of the methadone bundled payment rate). The non-drug component of both the injectable buprenorphine bundled payment rate (HCPCS code GXXX3) and the injectable naltrexone bundled rate (HCPCS code GXXX7) is $117.40 ($110.96 minus a $10.50 dispensing fee plus a $16.94 administration fee). The non-drug components of the buprenorphine implant bundled payment rates (HCPCS codes GXXX4, GXXX5, and GXXX6 for implant insertion, removal, and insertion and removal, respectively) are $211.46, $227.32, and $305.16, respectively ($110.96 minus a $10.50 dispensing fee plus the corresponding PFS non-facility rate for implant insertion, removal, and insertion and removal, HCPCS codes G0516, G0517, and G0518, which are $111.00, $126.86, and $204.70, respectively). The rate for the no medication bundled payment (HCPCS code GXXX8) is $100.46 ($110.96 minus a $10.50 dispensing fee). As described in further detail above, we are proposing that the codes describing a medication not otherwise specified (HCPCS codes GXXX9 and GXX18) would be priced according to the methodology described above based on whether the medication is oral, injectable or implantable (based on a crosswalk to the TRICARE rate, adjusted for any applicable administration and dispensing fees). The non-drug component of the codes describing partial episodes (HCPCS codes GXX10, GXX11, GXX12, GXX13, GXX14, GXX15, and GXX16) are calculated as described in further detail above, based on a crosswalk to half of the rate for non-drug services included in the TRICARE weekly bundled payment (adjusted to account for administration and dispensing of that drug. Finally, the non-drug component for HCPCS code GXX19 is calculated based on rates set by state Medicaid programs for similar services. All non-drug components of the valuations would be geographically adjusted as discussed in the locality adjustment section of this proposed rule.

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(8) Place of Service (POS) Code for Services Furnished at OTPs

We are creating a new POS code specific to OTPs since there are no existing POS codes that specifically describe OTPs. Claims for OTP services would include this place of service code. We note that POS codes are available for use by all payers. We are not proposing to make any differential payment based on the use of this new POS code. Further guidance will be issued regarding the POS code that should be used by OTPs.

c. Duplicative Payments Under Parts B or D

Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Part B or Part D for items and services furnished by an OTP. We note that many of the individual items or services provided by OTPs that would be included in the bundled payment rates under our proposal may also be appropriately available to beneficiaries through other Medicare benefits. Although we recognize the potential for significant program integrity concerns when similar items or services are payable under separate Medicare benefits, we also believe that it is important that any efforts to prevent duplicative payments not inadvertently restrict Medicare beneficiaries' access to other Medicare benefits even for the time period they are being treated by an OTP. For example, we believe that a beneficiary receiving counseling or therapy as part of an OTP bundle of services may also be receiving medically reasonable and necessary counseling or therapy as part of a physician's service during the same time period. Similarly, we believe there could be circumstances where Medicare beneficiaries with OUD could receive treatment and/or medication from non-OTP entities that would not result in duplicative payments, presuming that both the OTP and the other entity appropriately furnished separate medically necessary services or items. Consequently, we do not believe that provision of the same kinds of services by both an OTP and a separate provider or supplier would itself constitute a duplicative payment.

We believe that duplicative payments would result from the submission of claims to Medicare leading to payment for drugs furnished to a Medicare beneficiary and the associated dispensing fees on a certain date of service to both an OTP and another provider or supplier under a different benefit. In these circumstances, we would consider only one of the claims to be paid for appropriately. Accordingly, for purposes of implementing section 1834(w)(1) of the Act, we propose to consider payment for medications delivered, administered or dispensed to the beneficiary as part of the OTP bundled payment to be a duplicative payment if delivery, administration or dispensing of the same medications was also separately paid under Medicare Parts B or D. We propose to codify this policy at § 410.67(d)(4). We understand that some OTPs negotiate arrangements whereby community pharmacies supply MAT-related medications to OTPs. If the OTP provides medically necessary MAT-related medications as part of an episode of care, we would expect the OTP to take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payment. (For example, the MAT drugs billed by an OTP as part of a bundled payment should not be reported to or paid under a Part D plan.) We expect that OTPs will take reasonable steps to ensure that the items and services furnished under their care are not reported or billed under a different Medicare benefit. CMS intends to monitor for duplicative payments, and would take appropriate action as needed when such duplicative payments are identified. Therefore, we are proposing that in cases where a payment for drugs used as part of an OTP's treatment plan is identified as being a duplicative payment because the same costs were paid under a different Medicare benefit, CMS will generally recoup the duplicative payment made to the OTP as the OTP would be in the best position to know whether or not the drug that is included as part of the beneficiary's treatment plan is furnished by the OTP or by another provider or supplier given that the OTP is responsible for managing the beneficiary's overall OUD treatment. We propose to codify this policy at § 410.67(d)(4). CMS notes that this general approach would not preclude CMS or other auditors from conducting appropriate oversight of duplicative payments made to the other provider or suppliers, particularly in cases of fraud and/or abuse.

d. Cost Sharing

Section 2005(c) of the SUPPORT Act amends section 1833(a)(1) of the Act, relating to payment of Part B services, by adding a new subparagraph (CC), which specifies with respect to OUD treatment services furnished by an OTP during an episode of care that the amount paid shall be equal to the amount payable under section 1834(w) of the Act less any copayment required as specified by the Secretary. Section 1834(w) of the Act, which was also added by section 2005(c) of the SUPPORT Act, requires that the Secretary pay an amount that is equal to 100 percent of a bundled payment under this part for OUD treatment services. Given these two provisions, we believe that there is flexibility for CMS to set the copayment amount for OTP services either at zero or at an amount above zero. Therefore, we are proposing to set the copayment at zero for a time-limited duration (for example, for the duration of the national opioid crisis), as we believe this would minimize barriers to patient access to OUD treatment services. Setting the copayment at zero also ensures OTP providers receive the full Medicare payment amount for Medicare beneficiaries if secondary payers are not available or do not pay the copayment, especially for those dually eligible for Medicare and Medicaid.[77] We intend to continue to monitor the opioid crisis in order to determine at what point in the future a copayment may be imposed. At such a time we deem appropriate, we would institute cost sharing through future notice and comment rulemaking. We welcome feedback from the public on our proposal to set the copayment at zero for a time-limited duration, such as for the duration of the national opioid crisis, and any other metrics CMS might consider using to determine when to start requiring a copayment. In developing our proposed approach, we also considered other alternatives, such as setting the copayment at a fixed fee calculated based on 20 percent of the payment rate for the bundle, consistent with the standard copayment requirement for other Part B services, or applying a flat dollar copayment amount similar to TRICARE's copayment; however, we recognize that setting the copayment for OUD services at a non-zero amount could create a barrier to access to treatment for many beneficiaries. We propose to codify the proposed copayment amount of zero at § 410.67(e). We welcome feedback on our proposal to set the copayment amount for OTP services at zero, and on the alternatives considered, including whether we should consider any of these alternatives for CY 2020 or future years.

Separately, we note that the Part B deductible would apply for OUD treatment services, as mandated for all Part B services by section 1833(b) of the Act.

4. Adjustments to Bundled Payment Rates for OUD Treatment Services

The costs of providing OUD treatment services will likely vary over time and depending on the geographic location where the services are furnished. Below we discuss our proposed adjustments to the bundled payment rates to account for these factors.

a. Locality Adjustment

Section 1834(w)(2) of the Act, as added by section 2005(c) of the SUPPORT Act provides that the Secretary may implement the bundled payment for OUD treatment services furnished by OTPs through one or more bundles based on the type of medications, the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determines appropriate. The cost for the provision of OTP treatment services, like many other healthcare services covered by Medicare, will likely vary across the country based upon the differing cost in a given geographic locality. To account for such geographic cost differences in the provision of services, in a number of payment systems, Medicare routinely applies geographic locality adjustments to the payment rates for particular services. As we believe OTP treatment services will also be subject to varying cost based upon the geographic locality where the services are furnished, we propose to apply a geographic locality adjustment to the bundled payment rate for OTP treatment services. Below, we discuss our proposed approach with respect to the drug component (which reflects payment for the drug) and the non-drug component (which reflects payment for all other services furnished to the beneficiary by the OTP, such as drug administration, counseling, toxicology testing, etc.) of the bundled payment.

(1) Drug Component

Because our proposed approaches for pricing the MAT drugs included in the bundles all reflect national pricing, and because there is no geographic adjustment factor applied to the payment of Part B drugs under the ASP methodology, we do not believe that it is necessary to adjust the drug component of the bundled payment rates for OTP services based upon geographic locality. Therefore, we are proposing not to apply a geographic locality adjustment to the drug component of the bundled payment rate for OTP services.

(2) Non-Drug Component

Unlike the national pricing of drugs, the costs for the services included in the non-drug component of the OTP bundled payment for OUD treatments are not constant across all geographic localities. For example, OTPs' costs for rent or employee wages could vary significantly across different localities and could potentially result in disparate costs for the services included in the non-drug component of OUD treatment services. Because the costs of furnishing the services included in the non-drug component of the OTP bundled payment for OUD treatment services will vary based upon the geographic locality in which the services are provided, we believe it would be appropriate to apply a geographic locality adjustment to the non-drug component of the bundled payments. We believe that the geographic variation in cost of the non-drug services provided by OTPs will be similar to the geographic variation in the cost of services furnished in physician offices. Therefore, to account for the differential costs of OUD treatment services across the country, we are proposing to adjust the non-drug component of the bundled payment rates for OUD treatment services using an approach similar to the established methodology used to geographically adjust payments under the PFS based upon the location where the service is furnished. The PFS currently provides for an adjustment to the payment for PFS services based upon the fee schedule area in which the service is provided through the use of Geographic Practice Cost Indices (GPCIs), which measure the relative cost differences among localities compared to the national average for each of the

[77] For those dually eligible individuals in the Qualified Medicare Beneficiary program (7.7 million of the 12 million dually eligible individuals in 2017), state Medicaid programs cover the Medicare Part A and B deductible and coinsurance. However, section 4714 of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides discretion for states to pay Medicare cost-sharing only if the Medicaid payment rate for the service is above the Medicare paid amount for the service. Since most states opt for this discretion, and most Medicaid rates are lower than Medicare's, states often do not pay the provider for the Medicare cost-sharing amount. Providers are further prohibited from collecting the Medicare cost-sharing amount from the beneficiary, effectively having to take a discount compared to the amount received for other Medicare beneficiaries.

three fee schedule components (work, PE, and malpractice).

Although we are proposing to adjust the non-drug component of the OUD treatment services using an approach similar to the established methodology used to adjust PFS payment for geographic locality, because GPCIs provide for the application of geographic locality adjustments to the three distinct components of PFS services, and the OTP bundled payment is a flat rate payment for all OUD treatment services furnished during an episode of care, a single factor would be required to apply the geographic locality adjustment to the non-drug component of the OTP bundled payment rate. Therefore, to apply a geographic locality adjustment to the non-drug component of the OTP bundled payment for OUD treatment services through a single factor, we are proposing to use the Geographic Adjustment Factor (GAF) at § 414.26. Specifically, we are proposing to use the GAF to adjust the payment for the non-drug component of the OTP bundled payment to reflect the costs of furnishing the non-drug component of OUD treatment services in each of the PFS fee schedule areas. The GAF is calculated using the GPCIs under the PFS, and is used to account for cost differences in furnishing physicians' services in differing geographic localities. The GAF is calculated for each fee schedule area as the weighted composite of all three GPCIs (work, PE, and malpractice) for that given locality using the national GPCI cost share weights. In developing this proposal, we also considered geographically adjusting the payment for the non-drug component of the OTP bundled payment using only the PE GPCI value for each fee schedule area. However, because the the non-drug component of OUD treatment services is comprised of work, PE, and malpractice expenses, we ultimately decided to propose using the GAF as we believe the weighted composite of all three GPCIs reflected in the GAF would be the more appropriate geographic adjustment factor to reflect geographic variations in the cost of furnishing these services.

The GAF, which is determined under § 414.26, is further discussed earlier in section II.D.1. of this proposed rule and the specific GAF values for each payment locality are posted in Addendum D to this proposed rule. In developing the proposed geographic locality adjustment for the non-drug component of the OUD treatment services payment rate, we also considered other potential locality adjustments, such as the Inpatient Prospective Payment System (IPPS) hospital wage index. However, we have opted to propose using the GAF as we believe the services provided in an OTP more closely resemble the services provided at a physician office than the services provided in other settings, such as inpatient hospitals. We propose to codify using the GAF to adjust the non-drug component of the OTP bundled payments to reflect the cost differences in furnishing these services in differing geographic localities at § 410.67(d)(3)(ii). We invite public comment on our proposal to adjust the non-drug component of the OTP bundled payments for geographic variations in the costs of furnishing OUD treatment services using the GAF. We also welcome comments on any factors, other than the GAF, that could be used to make this payment adjustment.

Additionally, we note that the majority of OTPs operate in urban localities. In light of this fact, we are interested in receiving information on whether rural areas have appropriate access to treatment for OUD. We are particularly interested in any potential limitations on access to care for OUD in rural areas and whether there are additional adjustments to the proposed bundled payments that should be made to account for the costs incurred by OTPs in furnishing OUD treatment services in rural areas. We invite public comment on this issue and potential solutions we could consider adopting to address this potential issue through future rulemaking.

b. Annual Update

Section 1834(w)(3) of the Act, as added by section 2005(c) of the SUPPORT Act, requires that the Secretary provide an update each year to the OTP bundled payment rates. To fulfill this statutory requirement, we are proposing to apply a blended annual update, comprised of distinct updates for the drug and non-drug components of the bundled payment rates, to account for the differing rate of growth in the prices of drugs relative to other services. We propose that this blended annual update for the OTP bundled payment rates would first apply for determining the CY 2021 OTP bundled payment rates. The specific details of the proposed updates for the drug and non-drug components respectively are discussed in this section.

(1) Drug Component

As stated above, we are proposing to establish the pricing of the drug component of the OTP bundled payment rates for OUD treatment services based on CMS pricing mechanisms currently in place. To recognize the potential change in costs of the drugs used in MAT from year to year and to fulfill the requirement to provide an annual update to the OTP bundled payment rates, we are proposing to update the payment for the drug component based upon the changes in drug costs reported under the pricing mechanism used to establish the pricing of the drug component of the applicable bundled payment rate, as discussed earlier. As an example, if we were to finalize our proposal to price the drug component of the bundled payment rate for episodes of care that include injectable and implantable drugs generally covered and paid under Medicare Part B using ASP data, the pricing of the drug component for these OTP bundled payments, would be updated using the most recently available ASP data at the time of ratesetting for the applicable calendar year. Similarly, if we finalize our proposal to price the drug component of the bundled payment rate for episodes of care that include oral drugs using ASP data, if such data are available, we would also update the pricing of the drug component using the most recently available ASP data at the time of ratesetting for the applicable calendar year. Previously, we also discussed a number of alternative data sources that could be used to price oral drugs in the drug component of OTP bundled payments in cases when we do not receive manufacturer-submitted ASP pricing data. As an example, if we were to use NADAC data as discussed as one of the alternatives, to determine the payment for the drug component of the bundled payment for oral drugs in cases when we do not have manufacturer-submitted ASP pricing data, this payment rate would also be updated using the most recently available NADAC data at the time of ratesetting for the applicable calendar year. We propose to codify this methodology for determining the annual update to the payment rate for the drug component at § 410.67(d)(3)(i).

In developing the proposal to annually update the pricing of the drug component of the OUD treatment services payment rate, we also considered other methodologies, including applying a single uniform update factor to the drug and non-drug components of the proposed payment rates. We ultimately determined not to propose the use of a single uniform update factor, because we believe that it is important to apply an annual update to the payment rates that recognizes the differing rate of growth of drug costs

compared to the rate of growth in the cost of the other services. In addition, we also considered annually updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the Producer Price Index (PPI) for chemicals and allied products, analgesics (WPU06380202). The PPI for chemicals and allied products, analgesics is a subset of the PPI produced by the Bureau of Labor Statistics, which measures the average change over time in the selling prices received by domestic producers for their output. Ultimately we decided against updating the pricing of the drug component of the OUD treatment services payment rate via an established update factor such as the PPI in favor of our proposed approach because we believe the proposed approach updated the pricing of the drug component of the OUD treatment services payment rate in the manner most familiar to stakeholders. We invite public comment on our proposed approach to updating the drug component of the bundled payment rates. We also seek comment on possible alternate methodologies for updating the drug component of the payment rate for OUD treatment services, such as use of the PPI for chemicals and allied products, analgesics.

(2) Non-Drug Component

To account for the potential changing costs of the services included in the non-drug component of the bundled payment rates for OUD treatment services, we are proposing to update the non-drug component of the bundled payment for OUD treatment services based upon the Medicare Economic Index (MEI). The MEI is defined in section 1842(i)(3) of the Act and the methodology for computing the MEI is described in § 405.504(d). The MEI is used to update the payment rates for physician services under section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973, may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such a higher level is justified by year-to-year economic changes. The MEI is a fixed-weight input price index that reflects the physicians' own time and the physicians' practice expenses, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. The MEI was last revised in the CY 2014 PFS final rule with comment period (78 FR 74264). In developing the proposed update factor for the non-drug component of the OUD treatment services payment rate, we considered other potential update factors, such as the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*) and the IPPS hospital market basket reduced by the multifactor productivity adjustment. The Consumer Price Index for All Items (CPI–U) is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. However, we concluded that a healthcare-specific update factor, such as the MEI, would be more appropriate for OTPs than the CPI–U, which measures general inflation, as the MEI would more accurately reflect the change in the prices of goods and services included in the non-drug component of the OTP bundled payments.

Similarly, we believe the MEI would be more appropriate than the IPPS market basket to update the non-drug component of the bundled payment rates as the services provided by an OTP more closely resemble the services provided at a physician office than the services provided by an inpatient hospital. Accordingly, we propose to update the payment amount for the non-drug component of each of the bundled payment rates for OUD treatment services furnished by OTPs based upon the most recently available historical annual growth in the MEI available at the time of rulemaking. We propose to codify this proposal at § 410.67(d)(3)(iii). We invite public comment on this proposal.

H. Bundled Payments Under the PFS for Substance Use Disorders

1. Background and Proposal

In the CY 2019 PFS proposed rule (83 FR 35730), we solicited comment on creating a bundled episode of care payment for management and counseling treatment for substance use disorders. We received approximately 50 comments on this topic, most of which were supportive of creating a separate bundled payment for these services. Some commenters recommended focusing the bundle on services related to medication assisted treatment (MAT) used in treatment for opioid use disorder (OUD). Several commenters also recommended that we establish higher payment amounts for patients with more complex needs who require more intensive services and management, and also expressed concern that an episode of care that limited the duration of treatment would not be conducive to treating OUD, given the chronic nature of this disorder. Other commenters recommended that we establish separate bundled payments for treatment of substance use disorders that does, and does not, involve MAT.

In response to the public comments, we are proposing to establish bundled payments for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. We note that, if a patient's treatment involves MAT, this proposed bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged. Additionally, payment for medically necessary toxicology testing would not be included in the proposed OUD bundle, and would continue to be billed separately under the Clinical Lab Fee Schedule. We are also proposing in this proposed rule to implement the new Medicare Part B benefit added by section 2005 of the SUPPORT Act for coverage of certain services furnished by Opioid Treatment Programs (OTPs) beginning in CY 2020. We believe the proposed bundled payment under the PFS for OUD treatment described below will create an avenue for physicians and other health professionals to bill for a bundle of services that is similar to the new bundled OUD treatment services benefit, but not furnished by an OTP. By creating a separate bundled payment for these services under the PFS, we hope to incentivize increased provision of counseling and care coordination for patients with OUD in the office setting, thereby expanding access to OUD care.

To implement this new bundled payment, we are proposing to create two HCPCS G-codes to describe monthly bundles of services that include overall management, care coordination, individual and group psychotherapy and counseling for office-based OUD treatment. Although we considered proposing weekly-reported codes to describe a bundle of services that would align with the proposed OTP bundle, we believe that monthly-reported codes will better align with the practice and billing of other types of care management services furnished in office settings and billed under the PFS (for example, behavioral health integration (BHI) services). We believe monthly-reported codes would be less administratively burdensome for practitioners, and more likely to be consistent with care management and prescribing patterns in the office setting (as compared with an OTP) given the increased use of long-acting MAT drugs (such as injectable naltrexone or

implanted buprenorphine) in the office setting compared to the OTP setting. Based on feedback we received through the comment solicitation, we are proposing to create a code to describe the initial month of treatment, which would include intake activities and development of a treatment plan, as well as assessments to aid in development of the treatment plan in addition to care coordination, individual therapy, group therapy, and counseling; a code to describe subsequent months of treatment including care coordination, individual therapy, group therapy, and counseling; and an add-on code that could be billed in circumstances when effective treatment requires additional resources for a particular patient that substantially exceed the resources included in the base codes. In other words, the add-on code would address extraordinary circumstances that are not contemplated by the bundled code. We acknowledge that the course of treatment for OUD is variable, and in some instances, the first several months of treatment may be more resource intensive. We welcome comments on whether we should consider creating a separately billable code or codes to describe additional resources involved in furnishing OUD treatment-related services after the first month, for example, when substantial revisions to the treatment plan are needed, and what resource inputs we might consider in setting values for such codes.

We believe that, in general, bundled payments create incentives to provide efficient care by mitigating incentives tied to volume of services furnished, and that these incentives can be undermined by creating separate billing mechanisms to account for higher resource costs for particular patients. However, we share some of the concerns raised by commenters that an OUD bundle should not inadvertently limit the appropriate amount of OUD care furnished to patients with varying medical needs. In consideration of this concern, we are proposing to create an add-on code to make appropriate payment for additional resource costs in order to mitigate the risks that the bundled OUD payment might limit clinically-indicated patient care for patients that require significantly more care than is in the range of what is typical for the kinds of care described by the base codes. However, we are also interested in comments regarding ways we might better stratify the coding for OUD treatment to reflect the varying needs of patients (based on complexity or frequency of services, for example) while maintaining the full advantage of the bundled payment, including increased efficiency and flexibility in furnishing care.

We anticipate that these services would often be billed by addiction specialty practitioners, but note that these codes are not limited to any particular physician or non-physician practitioner specialty. Additionally, unlike the codes that describe care furnished using the psychiatric collaborative care model (CPT codes 99492, 99493, and 99494), which require consultation with a psychiatric consultant, we are not proposing to require consultation with a specialist as a condition of payment for these codes.

The codes and descriptors for the proposed services are:

- HCPCS code GYYY1: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code GYYY2: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code GYYY3: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

For the purposes of valuation for HCPCS codes GYYY1 and GYYY2, we are assuming two individual psychotherapy sessions per month and four group psychotherapy sessions per month; however, we understand that the number of therapy and counseling sessions furnished per month will vary among patients and also fluctuate over time based on the individual patient's needs. Consistent with the methodology for pricing other services under the PFS, HCPCS codes GYYY1, GYYY2, and GYYY3 are valued based on what we believe to be a typical case, and we understand that based on variability in patient needs, some patients will require more resources, and some fewer. In order to maintain the advantages inherent in developing a payment bundle, we are proposing that the add-on code (HCPCS code GYYY3) can only be billed when the total time spent by the billing professional and the clinical staff furnishing the OUD treatment services described by the base code exceeds double the minimum amount of service time required to bill the base code for the month. We believe it is appropriate to limit billing of the add-on code to situations where medically necessary OUD treatment services for a particular patient exceed twice the minimum service time for the base code because, as noted above, the add-on code is intended to address extraordinary situations where effective treatment requires additional resources that substantially exceed the resources included in the base codes. For example, the needs of a particular patient in a month may be unusually acute, well beyond the needs of the typical patient; or there may be some months when psychosocial stressors arise that were unforeseen at the time the treatment plan was developed, but warrant additional or more intensive therapy services for the patient. We are proposing that when the time requirement is met, HCPCS code GYYY3 could be billed as an add-on code during the initial month or subsequent months of OUD treatment. Practitioners should document the medical necessity for the use of the add-on code in the patient's medical record. We welcome comments on this proposal.

We are proposing to value HCPCS codes GYYY1, GYYY2, and GYYY3 using a building block methodology that sums the work RVUs and direct PE inputs from codes that describe the component services we believe would be typical, consistent with the approach we have previously used in valuing monthly care management services that include face-to-face services within the payment. For HCPCS code GYYY1, we developed proposed inputs using a crosswalk to CPT code 99492 (*Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric*

consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.), which is assigned a work RVU of 1.70, plus CPT code 90832 (*Psychotherapy, 30 minutes with patient*), which is assigned a work RVU of 1.50 (assuming two over the course of the month), and CPT code 90853 (*Group psychotherapy (other than of a multiple-family group)*), which is assigned a work RVU of 0.59 (assuming four over the course of a month), for a work RVU of 7.06. The required minimum number of minutes described in HCPCS code GYYY1 is also based on a crosswalk to CPT codes 99492. Additionally, for HCPCS code GYYY1, we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99492, CPT code 90832 (times two), and CPT code 90853 (times four). We believe that the work and practice expense described by these crosswalk codes is analogous to the services described in HCPCS code GYYY1 because HCPCS code GYYY1 includes similar care coordination activities as described in CPT code 99492 and bundles in the psychotherapy services described in CPT codes 90832 and 90853.

We are proposing to value HCPCS code GYYY2 using a crosswalk to CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*), which is assigned a work RVU of 1.53, plus CPT code 90832, which is assigned a work RVU of 1.50 (assuming two over the course of the month), and CPT code 90853, which is assigned a work RVU of 0.59 (assuming four over the course of a month), for a work RVU of 6.89. The required minimum number of minutes described in HCPCS code GYYY2 is also based on a crosswalk to CPT codes 99493. For HCPCS code GYYY2, we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99493, CPT code 90832 (times two), and CPT code 90853 (times four). We believe that the work and practice expense described by these crosswalk codes is analogous to the services described in HCPCS code GYYY2 because HCPCS code GYYY2 includes similar care coordination activities as described in CPT code 99493 and bundles in the psychotherapy services described in CPT codes 90832 and 90853.

We are proposing to value HCPCS code GYYY3 using a crosswalk to CPT code 99494 (*Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (List separately in addition to code for primary procedure)*), which is assigned a work RVU of 0.82. The required minimum number of minutes described in HCPCS code GYYY2 is also based on a crosswalk to CPT codes 99493. For HCPCS code GYYY3, we are proposing to use a crosswalk to the direct PE inputs associated with CPT code 99494. We believe that the work and practice expense described by this crosswalk code is analogous to the services described in HCPCS code GYYY3 because HCPCS code GYYY3 includes similar care coordination activities as described in CPT code 99494.

For additional details on the proposed direct PE inputs for HCPCS codes GYYY1–GYYY3, *see* Table 22.

We understand that many beneficiaries with OUD have comorbidities and may require medically-necessary psychotherapy services for other behavioral health conditions. In order to avoid duplicative billing, we are proposing that, when furnished to treat OUD, CPT codes 90832, 90834, 90837, and 90853 may not be reported by the same practitioner for the same beneficiary in the same month as HCPCS codes GYYY1, GYYY2, and GYYY3. We welcome comments on this proposal.

We are proposing that practitioners reporting the OUD bundle must furnish a separately reportable initiating visit in association with the onset of OUD treatment, since the bundle requires a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs. This is similar to the requirements for chronic care management (CCM) services (CPT codes 99487, 99489, 99490, and 99491) and BHI services (CPT codes 99484, 99492, 99493, and 99494) finalized in the CY 2017 PFS final rule (81 FR 80239) The initiating visit would establish the beneficiary's relationship with the billing practitioner, ensure the billing practitioner assesses the beneficiary to determine clinical appropriateness of MAT in cases where MAT is being furnished, and provide an opportunity to obtain beneficiary consent to receive care management services (as discussed further below). We propose that the same services that can serve as the initiating visit for CCM services and BHI services can serve as the initiating visit for the proposed services described by HCPCS codes GYYY1–GYYY3. For new patients or patients not seen by the practitioner within a year prior to the commencement of CCM services and BHI services, the billing practitioner must initiate the service during a ''comprehensive'' E/M visit (levels 2 through 5 E/M visits), annual wellness visit (AWV) or initial preventive physical exam (IPPE). The face-to-face visit included in transitional care management (TCM) services (CPT codes 99495 and 99496) also qualifies as a ''comprehensive'' visit for CCM and BHI initiation. We propose that these visits could similarly serve as the initiating visit for OUD services.

We are proposing that the counseling, therapy, and care coordination described in the proposed OUD treatment codes could be provided by professionals who are qualified to provide the services under state law and within their scope of practice ''incident to'' the services of the billing physician or other practitioner. We are also proposing that the billing clinician would manage the patient's overall care, as well as supervise any other individuals participating in the treatment, similar to the structure of the BHI codes describing the psychiatric collaborative care model finalized in the CY 2017 PFS final rule (81 FR 80229), in which services are reported by a treating physician or other qualified health care professional and include the services of the treating physician or other qualified health care professional,

as well as the services of other professionals who furnish services incident to the services of the treating physician or other qualified health care professional. Additionally, we are proposing to add these codes to the list of designated care management services for which we allow general supervision of the non-face-to-face portion of the required services. Consistent with policies for other separately billable care management services under the PFS, because these proposed OUD treatment bundles include non-face-to-face care management components, we are proposing that the billing practitioner or clinical staff must document in the beneficiary's medical record that they obtained the beneficiary's consent to receive the services, and that, as part of the consent, they informed the beneficiary that there is cost sharing associated with these services, including potential deductible and coinsurance amounts, for both in-person and non-face-to-face services that are provided.

We are also proposing to allow any of the individual therapy, group therapy and counseling services included in HCPCS codes GYYY1, GYYY2, and GYYY3 to be furnished via telehealth, as clinically appropriate, in order to increase access to care for beneficiaries. As discussed in section II.F. of this proposed rule regarding Telehealth Services, like certain other non-face-to-face PFS services, the components of HCPCS codes GYYY1 through GYYY3 describing care coordination are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, these services are not considered telehealth services for purposes of Medicare, and we do not need to consider whether the non-face-to-face aspects of HCPCS codes GYYY1 through GYYY3 are similar to other telehealth services. If the non-face-to-face components of HCPCS codes GYYY1 through GYYY3 were separately billable, they would not need to be on the Medicare telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology.

Section 2001(a) of the SUPPORT Act amended section 1834(m) of the Act, adding a new paragraph (7) that removes the geographic limitations for telehealth services furnished on or after July 1, 2019, to an individual with a substance use disorder (SUD) diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder. The new paragraph at section 1834(m)(7) of the Act also allows telehealth services for treatment of a diagnosed SUD or co-occurring mental health disorder to be furnished to individuals at any telehealth originating site (other than a renal dialysis facility), including in a patient's home. As discussed in section II.F. of this proposed rule, Telehealth Services, we are proposing to add HCPCS codes GYYY1, GYYY2, and GYYY3 to the list of Medicare Telehealth services. Because certain required services (such as individual psychotherapy or group psychotherapy services) that are included in the proposed OUD bundled payment codes would be furnished to treat a diagnosed SUD, and would ordinarily require a face-to-face encounter, they could be furnished more broadly as telehealth services as permitted under section 1834(m)(7) of the Act.

For these proposed services described above (HCPCS codes GYYY1, GYYY2, and GYYY3), we seek comment on how these potential codes, descriptors, and payment rates align with state Medicaid coding and payment rates for the purposes of state payment of cost sharing for Medicare-Medicaid dually eligible individuals. Additionally, we understand that treatment for OUD can vary, and that MAT alone has demonstrated efficacy. In cases where a medication such as buprenorphine or naltrexone is used to treat OUD alone, without therapy or counseling, we note that existing applicable codes can be used to furnishing and bill for that care (for example, using E/M visits, in lieu of billing the bundled OUD codes proposed here).

As discussed in section II.G. of this proposed rule, Medicare Coverage for Certain Services Furnished by Opioid Treatment Programs, we are proposing to set the copayment at zero for OUD services furnished by an OTP, given the flexibility in section 1834(w)(1) of the Act for us to set the copayment amount for OTP services either at zero or at an amount above zero. We note that we do not have the statutory authority to eliminate the deductible and coinsurance requirements for the bundled OUD treatment services under the PFS. We acknowledge the potential impact of coinsurance on patient health care decisions and intend to monitor its impact if these proposals were to be finalized.

Finally, we recognize that historically, the CPT Editorial Panel has frequently created CPT codes describing services that we originally established using G-codes and adopted them through the CPT Editorial Panel process. We note that we would consider new using any available CPT coding to describe services similar to those described here in future rulemaking, as early as CY 2021. We would consider and adopt any such CPT codes through subsequent rulemaking.

Additionally, we understand that in some cases, OUD can first become apparent to practitioners in the emergency department setting. We recognize that there is not specific coding that describes diagnosis of OUD or the initiation of, or referral for, MAT in the emergency department setting. We are seeking comment on the use of MAT in the emergency department setting, including initiation of MAT and the potential for either referral or follow-up care, as well as the potential for administration of long-acting MAT agents in this setting, in order to better understand typical practice patterns to help inform whether we should consider making separate payment for such services in future rulemaking. We welcome feedback from stakeholders and the public on other potential bundles describing services for other substance use disorders for our consideration in future rulemaking.

2. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

In the CY 2018 PFS final rule (82 FR 53169 through 53180), we established payment for General Care Management (CCM) services using HCPCS G0511 which is an RHC and FQHC-specific G code for at least 20 minutes of CCM, complex CCM, or general behavioral health services. Payment for this code is currently set at the average of the non-facility, non-geographically adjusted payment rates for CPT codes 99490, 99487, 99491, and 99484. The types of chronic conditions that are eligible for care management services include mental health or behavioral health conditions, including substance use disorders.

In the CY 2018 PFS final rule with comment period (82 FR 53169 through 53180), we also established payment for psychiatric Collaborative Care Services (CoCM) using HCPCS code G0512, which is an RHC and FQHC specific G-code for at least 70 minutes in the first calendar month, and at least 60 minutes in subsequent calendar months of psychiatric CoCM services. Payment for this code is set at the average of the non-facility, non-geographically adjusted rates for CPT codes 99492 and 99493. The psychiatric CoCM model of care may be used to treat patients with any behavioral health condition that is being treated by the billing practitioner, including substance use disorders.

RHCs and FQHCs can also bill for individual psychotherapy services using CPT codes 90791, 90792, 90832, 90834, 90837, 90839, or 90845, which are billable visits under the RHC all-inclusive rate (AIR) and FQHC Prospective Payment System (PPS) when furnished by an RHC or FQHC practitioner. If a qualified mental health service is furnished on the same day as a qualified primary care service, the RHC or FQHC can bill for 2 visits.

RHCs and FQHCs are engaged primarily in providing services that are furnished typically in a physician's office or an outpatient clinic. As a result of the proposed bundled payment under the PFS for OUD treatment furnished by physicians, we reviewed the applicability of RHCs and FQHCs furnishing and billing for similar services. Specifically, we considered establishing a new RHC and FQHC specific G code for OUD treatment with the payment rate set at the average of the non-facility, non-geographically adjusted payment rates for GYYY1 and GYYY2, beginning on January 1, 2020. The requirements to bill the services would be similar to the requirements under the PFS for GYYY1 and GYYY2, including that an initiating visit with a primary care practitioner must occur within one year before OUD services begin, and that consent be obtained before services are furnished.

However, because RHCs and FQHCs that choose to furnish OUD services can continue to report these individual codes when treating OUD, and can also offer their patients comprehensive care coordination services using HCPCS codes G0511 and G0512, we do not believe that adding a new and separate code to report a bundle of OUD services is necessary. Therefore, we are not proposing to add a new G code for a bundle of OUD service.

I. Physician Supervision for Physician Assistant (PA) Services

1. Background

Section 4072(e) of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509, October 21, 1986), added section 1861(s)(2)(K)(i) of the Act to establish a benefit for services furnished by a physician assistant (PA) under the supervision of a physician. We have interpreted this physician supervision requirement in the regulation at § 410.74(a)(2)(iv) to require PA services to be furnished under the general supervision of a physician. This general supervision requirement was based upon another longstanding regulation at § 410.32(b)(3)(i) that defines three levels of supervision for diagnostic tests, which are general, direct and personal supervision. Of these three supervision levels, general supervision is the most lenient. Specifically, the general supervision requirement means that PA services must be furnished under a physician's overall direction and control, but the physician's presence is not required during the performance of PA services.

In the CY 2018 PFS proposed rule (82 FR 34172 through 34173), we published a request for information (RFI) on CMS flexibilities and efficiencies. In response to this RFI, commenters including PA stakeholders informed us about recent changes in the practice of medicine for PAs, particularly regarding physician supervision. These commenters also reached out separately to CMS with their concerns. They stated that PAs are now practicing more autonomously, like nurse practitioners (NPs) and clinical nurse specialists (CNSs), as members of medical teams that often consist of physicians, nonphysician practitioners and other allied health professionals. This changed approach to the delivery of health care services involving PAs has resulted in changes to scope of practice laws for PAs regarding physician supervision across some states. According to these commenters, some states have already relaxed their requirements for PAs related to physician supervision, some states have made changes and are now silent about their physician supervision requirements, while other states have not yet changed their PA scope of practice in terms of their physician supervision requirements. Overall, these commenters believe that as states continue to make changes to their physician supervision requirements for PAs, the Medicare requirement for general supervision of PA services may become increasingly out of step with current medical practice, imposing a more stringent standard than state laws governing physician supervision of PA services. Furthermore, as currently defined, stakeholders have suggested that the supervision requirement is often misinterpreted or misunderstood in a manner that restricts PAs' ability to practice to the full extent of their education and expertise. The stakeholders have suggested that the current regulatory definition of physician supervision as it applies to PAs could inappropriately restrict the practice of PAs in delivering their professional services to the Medicare population.

We note that we have understood our current policy to require general physician supervision for PA services to fulfill the statutory physician supervision requirement; and we believe that general physician supervision gives PAs flexibility to furnish their professional services without the need for a physician's physical presence or availability. Nonetheless, we appreciate the concerns articulated by stakeholders. To more fully understand the current landscape for medical practice involving PA services and how the current regulatory definition may be problematic, we invite public comments on specific examples of changes in state law and state scope of practice rules that enable PAs to practice more broadly such that those rules are in tension with the Medicare requirement for general physician supervision of PA services that has been in place since the inception of the PA benefit category under Medicare law.

Given the commenters' understanding of ongoing changes underway to the state scope of practice laws regarding physician supervision of PA services, commenters on our CY 2018 RFI have requested that CMS reconsider its interpretation of the statutory requirement that PA services must be furnished under the supervision of a physician to allow PAs to operate similarly to NPs and CNSs, who are required by section 1861(s)(2)(K)(ii) of the Act to furnish their services ''in collaboration'' with a physician. In general, we have interpreted collaboration for this purpose at §§ 410.75(c)(3) and 410.76(c)(3) of our regulations to mean a process in which an NP or CNS (respectively) works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided by state law in which the services are performed. The commenters stated that allowing PA services to be furnished using such a collaborative process would offer PAs the flexibility necessary to deliver services more effectively under today's health care system in accordance with the scope of practice in the state(s) where they practice, rather than being limited by the system that was in place when PA services were first covered under Medicare Part B over 30 years ago.

2. Proposal

After considering the comments we received on the RFI, as well as information we received regarding the scope of practice laws in some states regarding supervision requirements for PAs, we are proposing to revise the regulation at § 410.74 that establishes physician supervision requirements for PAs. Specifically, we are proposing to

revise § 410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services. Consistent with current rules, such documentation would need to be available to CMS, upon request. This proposed change would substantially align the regulation on physician supervision for PA services at § 410.74(a)(2) with our current regulations on physician collaboration for NP and CNS services at §§ 410.75(c)(3) and 410.76(c)(3). We continue to engage with key stakeholders on this issue and receive information on the expanded role of nonphysician practitioners as members of the medical team. As we are informed about transitions in state law and state scope of practice governing physician supervision, as well as changes in the way that PAs practice, we acknowledge the state's role and autonomy to establish, uphold, and enforce their state laws and PA scope of practice requirements to ensure that an appropriate level of physician oversight occurs when PAs furnish their professional services to Medicare Part B patients. Our policy proposal on this issue largely defers to state law and state scope of practice and enables states the flexibility to develop requirements for PA services that are unique and appropriate for their respective state, allowing the states to be accountable for the safety and quality of health care services that PAs furnish.

J. Review and Verification of Medical Record Documentation

1. Background

In an effort to reduce mandatory and duplicative medical record evaluation and management (E/M) documentation requirements, we finalized an amended regulatory provision at 42 CFR part 415, subpart D, in the CY 2019 PFS final rule (83 FR 59653 through 59654). Specifically, § 415.172(a) requires as a condition of payment under the PFS that the teaching physician (as defined in § 415.152) must be present during certain portions of services that are furnished with the involvement of residents (individuals who are training in a graduate medical education program). Section 415.174(a) provides for an exception to the teaching physician presence requirements in the case of certain E/M services under certain conditions, but requires that the teaching physician must direct and review the care provided by no more than four residents at a time. Sections 415.172(b) and 415.174(a)(6), respectively require that the teaching physician's presence and participation in services involving residents must be documented in the medical record. We amended these regulations to provide that a physician, resident, or nurse may document in the patient's medical record that the teaching physician presence and participation requirements were met. As a result, for E/M visits furnished beginning January 1, 2019, the extent of the teaching physician's participation in services involving residents may be demonstrated by notes in the medical records made by a physician, resident, or nurse.

For the same burden reduction purposes, we issued CR 10412, Transmittal 3971 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3971CP.pdf* on February 2, 2018, which revised a paragraph in our manual instructions on ''Teaching Physician Services'' at Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B., to reduce duplicative documentation requirements by allowing a teaching physician to review and verify (sign/date) notes made by a student in a patient's medical record for E/M services, rather than having to re-document the information, largely duplicating the student's notes. We issued corrections to CR 10412 through Transmittal 4068 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4068CP.pdf* and re-issued the CR on May 31, 2018. Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100 contains a list of definitions pertinent to teaching physician services. Following these amendments to our regulations and manual, certain stakeholders raised concerns about the definitions in this section, particularly those for teaching physician, student, and documentation; and when considered in conjunction with the interpretation of the manual provision at Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 100.1.1B., which addresses documentation of E/M services involving students. While there is no regulatory definition of student, the manual instruction defines a student as an individual who participates in an accredited educational program (for example, a medical school) that is not an approved graduate medical education (GME) program. The manual instructions also specify that a student is never considered to be an intern or a resident, and that Medicare does not pay for services furnished by a student (*see* Section 100.1.1B. for a discussion concerning E/M service documentation performed by students).

We are aware that nonphysician practitioners who are authorized under Medicare Part B to furnish and be paid for all levels of E/M services are seeking similar relief from burdensome E/M documentation requirements that would allow them to review and verify medical record notes made by their students, rather than having to re-document the information. These nonphysician practitioners include nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse-midwives (CNMs), collectively referred to hereafter for purposes of this discussion as advanced practice registered nurses (APRNs), as well as physician assistants (PAs). Subsequent to the publication of the CY 2019 PFS final rule (83 FR 59653 through 59654), through feedback from listening sessions hosted by CMS' Documentation Requirements Simplification workgroup, we began to hear concerns from a variety of stakeholders about the requirements for teaching physician review and verification of documentation added to the medical record by other individuals. Physician and nonphysician practitioner stakeholders expressed concern about the scope of the changes to §§ 415.172(b) and 415.174(a)(6) which authorize only a physician, resident, or nurse to include notes in the medical record to document E/M services furnished by teaching physicians, because they believed that students and other members of the medical team should be similarly permitted to provide E/M medical record documentation. In addition to students, these stakeholders indicated that ''other members of the medical team'' could include individuals who the teaching physician, other physicians, PA and APRN preceptors designate as being appropriate to document services in the medical record, which the billing practitioner would then review and verify, and rely upon for billing purposes.

Subsequent to the publication of the student documentation manual

instruction change at section 100.1.1B of the Medicare Claims Processing Manual, representatives of PAs and APRNs requested clarification about whether PA and APRN preceptors and their students were subject to the same E/M documentation requirements as teaching physicians and their medical students. These stakeholders suggested that the reference to ''student'' in the manual instruction on E/M documentation provided by students is ambiguous because it does not specify ''medical student''. These stakeholders also suggested that the definition of ''student'' in section 100 of this manual instruction is ambiguous because PA and APRN preceptors also educate students who are individuals who participate in an accredited educational program that is not an approved GME program. Accordingly, these stakeholders expressed concern that the uncertainty throughout the health care industry, including among our contractors, concerning the student E/M documentation review and verification policy under these manual guidelines results in unequal treatment as compared to teaching physicians. The stakeholders stated that depending on how the manual instruction is interpreted, PA and APRN preceptors may be required to re-document E/M services in full when their students include notes in the medical records, without having the same option that teaching physicians do to simply review and verify medical student documentation.

2. Proposal

After considering the concerns expressed by these stakeholders, we believe it would be appropriate to provide broad flexibility to the physicians, PAs and APRNs (regardless of whether they are acting in a teaching capacity) who document and who are paid under the PFS for their professional services. Therefore, we propose to establish a general principle to allow the physician, the PA, or the APRN who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. This principle would apply across the spectrum of all Medicare-covered services paid under the PFS. Because this proposal is intended to apply broadly, we propose to amend regulations for teaching physicians, physicians, PAs, and APRNs to add this new flexibility for medical record documentation requirements for professional services furnished by physicians, PAs and APRNs in all settings. We invite comments on this proposal.

Specifically, to reflect our simplified and standardized approach to medical record documentation for all professional services furnished by physicians, PAs and APRNs paid under the PFS, we are proposing to amend §§ 410.20 (Physicians' services), 410.74 (PA services), 410.75 (NP services), 410.76 (CNS services) and 410.77 (CNM services) to add a new paragraph entitled, ''Medical record documentation.'' This paragraph would specify that, when furnishing their professional services, the clinician may review and verify (sign/date) notes in a patient's medical record made by other physicians, residents, nurses, students, or other members of the medical team, including notes documenting the practitioner's presence and participation in the services, rather than fully re-documenting the information. We note that, while the proposed change addresses who may document services in the medical record, subject to review and verification by the furnishing and billing clinician, it does not modify the scope of, or standards for, the documentation that is needed in the medical record to demonstrate medical necessity of services, or otherwise for purposes of appropriate medical recordkeeping.

We are also proposing to make conforming amendments to §§ 415.172(b) and 415.174(a)(6) to also allow physicians, residents, nurses, students, or other members of the medical team to enter information in the medical record that can then be reviewed and verified by a teaching physician without the need for re-documentation. We invite comments on these proposed amendments to our regulations.

K. Care Management Services

1. Background

In recent years, we have updated PFS payment policies to improve payment for care management and care coordination. Working with the CPT Editorial Panel and other clinicians, we have expanded the suite of codes describing these services. New CPT codes were created that distinguish between services that are face-to-face; represent a single encounter, monthly service or both; are timed services; represent primary care versus specialty care; address specific conditions; and represent the work of the billing practitioner, their clinical staff, or both (*see* Table 16). Additional information regarding recent new codes and associated PFS payment rules is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.*

TABLE 16—SUMMARY OF SPECIAL CARE MANAGEMENT CODES

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS Codes G0181, G0182).	Supervision of home health, hospice, per month.
ESRD Monthly Services (CPT Codes 90951–70)	ESRD management, with and without face-to-face visits, by age, per month.
Transitional Care Management (TCM) (adopted in 2013) (CPT Codes 99495, 99496).	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge.
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019) (CPT Codes 99487, 99489, 99490, 99491).	Management of all care for patients with two or more serious chronic conditions, timed, per month.
Advance Care Planning (ACP) (adopted in 2016) (CPT Codes 99497, 99498).	Counseling/discussing advance directives, face-to-face, timed.
Behavioral Health Integration (BHI) (adopted in 2017) (CPT Codes 99484, 99492, 99493, 99494).	Management of behavioral health conditions(s), timed, per month.
Assessment/Care Planning for Cognitive Impairment (adopted in 2017) (CPT Code 99483).	Assessment and care planning of cognitive impairment, face-to-face visit.
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT Codes 99358, 99359).	Non-face-to-face E&M work related to a face-to-face visit, timed.

TABLE 16—SUMMARY OF SPECIAL CARE MANAGEMENT CODES—Continued

Service	Summary
Remote Patient Monitoring (adopted in 2019) (CPT Code 99091)	Review and analysis of patient-generated health data, timed, per 30 days.
Interprofessional Consultation (adopted in 2019) (CPT Codes 99446, 99447, 99448, 99449, 99451, 99452).	Inter-practitioner consultation.

Based on our review of the Medicare claims data we estimate that approximately 3 million unique beneficiaries (9 percent of the Medicare fee-for-service (FFS) population) receive these services annually, with higher use of chronic care management (CCM), transitional care management (TCM), and advance care planning (ACP) services. We believe gaps remain in coding and payment, such as for care management of patients having a single, serious, or complex chronic condition. In this proposed rule, we continue our ongoing work in this area through code set refinement related to TCM services and CCM services, in addition to proposing new coding for principal care management (PCM) services, and addressing chronic care remote physiologic monitoring (RPM) services.

2. Transitional Care Management (TCM) Services

Utilization of TCM services has increased each year since CMS established coding and began paying separately for TCM services. Specifically, there were almost 300,000 TCM professional claims during 2013, the first year of TCM services, and almost 1.3 million professional claims during 2018, the most recent year of complete claims data. However, based upon an analysis of claims data by Bindman and Cox,[78] utilization of TCM services is low when compared to the number of Medicare beneficiaries with eligible discharges. Additionally, Bindman and Cox noted that the beneficiaries who received TCM services demonstrated reduced readmission rates, lower mortality, and decreased health care costs. Based upon these findings, we believe that increasing utilization of TCM services could positively affect patient outcomes.

In developing a proposal designed to increase utilization of TCM services, we considered possible factors contributing to low utilization. Bindman and Cox identified two likely contributing factors: The administrative burdens associated with billing TCM services and the payment amount to physicians for services.

We focused initially on the requirements for billing TCM services. In reviewing the TCM billing requirements, we noted that we had established in the CY 2013 PFS final rule with comment period a list of 57 HCPCS codes that cannot be billed during the 30-day period covered by TCM services by the same practitioner reporting TCM (77 FR 68990). This list mirrored reporting restrictions put in place by the CPT Editorial Panel for the TCM codes upon their creation. At the time we established separate payment for the TCM CPT codes, we agreed with the CPT Editorial Panel that the services described by the 57 codes could be overlapping and duplicative with TCM in their definition and scope; although, many of these codes were not separately payable or covered under the PFS so even if they were reported for PFS payment, they would not be have been separately paid (*see,* for example, 77 FR 68985). In response to those concerns, we adopted billing restrictions to avoid duplicative billing and payment for covered services. In our recent analysis of the services associated with the 57 codes, we found that the majority of codes on the list remain either bundled, noncovered by Medicare, or invalid for Medicare payment purposes. Table 17 provides detailed information regarding the subset of these codes that would be separately payable under the PFS (Status Indicator ''A'') and, as such, are the focus of this year's CY 2020 proposed policy for TCM. Fourteen (14) codes on the list represent active codes that are paid separately under the PFS and that upon reconsideration, we believe may not substantially overlap with TCM services and should be separately payable alongside TCM. For example, CPT code 99358 (*Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service*) would allow the physician or other qualified healthcare professional extra time to review records and manage patient support services after the face-to-face visit required as part of TCM services. CPT code 99091 (*Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days*) would permit the physician or other qualified healthcare professional to collect and analyze physiologic parameters associated with the patient's chronic disease.

Thus, after review of the services described by these 14 HCPCS codes, we believe these codes, when medically necessary, may complement TCM services rather than substantially overlap or duplicate services. We also believe removing the billing restrictions associated with these codes may increase utilization of TCM services.

TABLE 17—14 HCPCS CODES THAT CURRENTLY CANNOT BE BILLED CONCURRENTLY WITH TCM BY THE SAME PRACTITIONER AND ARE ACTIVE CODES PAYABLE BY MEDICARE PFS

Code family	HCPCS code	Descriptor
Prolonged Services without Direct Patient Contact.	99358	Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service.
	99359	Prolonged E/M service before and/or after direct patient care; each additional 30 minutes beyond the first hour of prolonged services.

[78] Bindman, AB, Cox DF. Changes in health care costs and mortality associated with transitional care management services after a discharge among Medicare beneficiaries [published online July 30, 2018]. *JAMA Intern Med,* doi:10.1001/jamainternmed.2018.2572.

TABLE 17—14 HCPCS CODES THAT CURRENTLY CANNOT BE BILLED CONCURRENTLY WITH TCM BY THE SAME PRACTITIONER AND ARE ACTIVE CODES PAYABLE BY MEDICARE PFS—Continued

Code family	HCPCS code	Descriptor
Home and Outpatient International Normalized Ratio (INR) Monitoring Services.	93792	Patient/caregiver training for initiation of home INR monitoring.
	93793	Anticoagulant management for a patient taking warfarin; includes review and interpretation of a new home, office, or lab INR test result, patient instructions, dosage adjustment and scheduling of additional test(s).
End Stage Renal Disease Services (patients who are 20+ years).	90960	ESRD related services monthly with 4 or more face-to-face visits per month; for patients 20 years and older.
	90961	ESRD related services monthly with 2–3 face-to-face visits per month; for patients 20 years and older.
	90962	ESRD related services with 1 face-to-face visit per month; for patients 20 years and older.
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older.
	90970	ESRD related services for dialysis less than a full month of service; per day; for patient 20 years and older.
Interpretation of Physiological Data	99091	Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days.
Complex Chronic Care Management Services.	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month.
	99489	Complex Chronic Care; additional 30 minutes of clinical staff time per month.
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities within a calendar month; 30+ minutes.
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (Pt not present) requiring complex and multidisciplinary care modalities; within a calendar month; 30+ minutes.

Thus, with the goal of increasing medically appropriate use of TCM services, we are proposing to revise our billing requirements for TCM by allowing TCM codes to be billed concurrently with any of these codes. Before we finalize such a rule, however, we seek comment on whether overlap of services exists, and if so, which services should be restricted from being billed concurrently with TCM. We also seek comment on whether any overlap would depend upon whether the same or a different practitioner reports the services. We note that CPT reporting rules generally apply at the practitioner level, and we are seeking input from stakeholders as to whether our policy should differ based on whether it is the same or a different practitioner reporting the services. We are seeking comment on whether the newest CPT code in the chronic care management services family (CPT code 99491 for CCM by a physician or other qualified health professional, established in 2019) overlaps with TCM or should be reportable and separately payable in the same service period.

As part of our analysis of the utilization data for TCM services, we also examined how current payment rates for TCM might negatively affect the appropriate utilization of TCM services, an idea proposed by Bindman and Cox. CPT code 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) and CPT code 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*) were resurveyed during 2018 as part of a regular RUC review of new technologies or services. For this RUC resurvey, several years of claims data were available and clinicians had more experience to inform their views about the work required to furnish TCM services. Based upon the results of the 2018 RUC survey of the two TCM codes, the RUC recommended a slight increase in work RVUs for both codes. We believe the results from the new survey will better reflect the work involved in furnishing TCM services as care management services. Thus, also for CY 2020, we are proposing the RUC-recommended work RVU of 2.36 for CPT code 99495 and the RUC-recommended work RVU of 3.10 for CPT code 99496. We are not proposing any direct PE refinements to the RUC's recommendations for this code family.

3. Chronic Care Management (CCM) Services

CCM services are comprehensive care coordination services per calendar month, furnished by a physician or non-physician practitioner (NPP) managing overall care and their clinical staff, for patients with two or more serious chronic conditions. There are currently two subsets of codes: One for non-complex chronic care management (starting in 2015, with a new code for 2019) and a set of codes for complex chronic care management (starting in 2017). Table 17 provides a high-level summary of the CCM service elements.

Early data show that, in general, CCM services are increasing patient and practitioner satisfaction, saving costs and enabling solo practitioners to remain in independent practice.[79] Utilization has reached approximately 75 percent of the level we initially assumed under the PFS when we began paying for CCM services separately under the PFS. While these are positive results, we believe that CCM services (especially complex CCM services) continue to be underutilized. In addition, we note that, at the February 2019 CPT Editorial Panel meeting, certain specialty associations requested refinements to the existing CCM codes, and consideration of their proposal was postponed. Also, we have heard from some stakeholders suggesting that the

[79] *https://innovation.cms.gov/Files/reports/chronic-care-mngmt-finalevalrpt.pdf.*

time increments for non-complex CCM performed by clinical staff should be changed to recognize finer increments of time, and that certain requirements related to care planning are unclear. Based on our consideration of this ongoing feedback, we believe some of the refinements requested by specialty associations and other stakeholders may be necessary to improve payment accuracy, reduce unnecessary burden and help ensure that beneficiaries who need CCM services have access to them. Accordingly, we are proposing the following changes to the CCM code set for CY 2020.

a. Non-Complex CCM Services by Clinical Staff (CPT Code 99490, HCPCS Codes GCCC1 and GCCC2)

Currently, the clinical staff CPT code for non-complex CCM, CPT code 99490 *(Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.)* describes 20 or more minutes of clinical staff time spent performing chronic care management activities under the direction of a physician/qualified health care professional. When we initially adopted this code for payment and, in feedback we have since received, a number of stakeholders suggested that CMS undervalued the PE RVU because we assumed that the minimum time for the code (20 minutes of clinical staff time) would be typical (see, for example, 79 FR 67717 through 67718). In the CY 2017 PFS final rule with comment period, we continued to consider whether the payment amount for CPT code 99490 is appropriate, given the amount of time typically spent furnishing CCM services (81 FR 80243 through 80244). We adopted the complex CCM codes for payment beginning in CY 2017, in part, to pay more appropriately for services furnished to beneficiaries requiring longer service times.

There are two CPT codes for complex CCM:

- CPT code 99487 *(Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately);* and
- CPT code 99489 *(each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).*

Complex CCM describes care management for patients who require not only more clinical staff time, but also complex medical decision-making. Some stakeholders continue to recommend that, in addition to separate payment for the complex CCM codes, we should create an add-on code for non-complex CCM, such that non-complex CCM would be defined and valued in 20-minute increments of time with additional payment for each additional 20 minutes, or extra payment for 20 to 40 minutes of clinical staff time spent performing care management activities.

We agree that coding changes that identify additional time increments would improve payment accuracy for non-complex CCM. Accordingly, we propose to adopt two new G codes with new increments of clinical staff time instead of the existing single CPT code (CPT code 99490). The first G code would describe the initial 20 minutes of clinical staff time, and the second G code would describe each additional 20 minutes thereafter. We intend these would be temporary G codes, to be used for PFS payment instead of CPT code 99490 until the CPT Editorial Panel can consider revisions to the current CPT code set. We would consider adopting any CPT code(s) once the CPT Editorial Panel completes its work. We acknowledge that imposing a transitional period during which G codes would be used under the PFS in lieu of the CPT codes is potentially disruptive, and are seeking comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.

We are proposing that the base code would be HCPCS code GCCC1 *(Chronic care management services, initial 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)).* We propose a work RVU of 0.61 for HCPCS code GCCC1, which we crosswalked from CPT code 99490. We believe these codes have a similar amount of work since they would have the same intra-service time of 15 minutes.

We propose an add-on HCPCS code GCCC2 *(Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC1, GCCC2 in the same calendar month as GCCC3, GCCC4, 99491)).* We are proposing a work RVU of 0.54 for HCPCS code GCCC2 based on a crosswalk to CPT code 11107 (*Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)*), which has a work RVU of 0.54, which we believe accurately reflects the work associated with each additional 20 minutes of CCM services. Both codes have the same intraservice time of 15 minutes. We note that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, codes need not share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. In this case, CPT code 11107 shares a similar work intensity to proposed HCPCS code GCCC2. Furthermore, although HCPCS codes GCCC1 and GCCC2 share the same intraservice time, add-on codes often have lower intensity than the base codes because they describe the continuation of an already initiated service.

We are soliciting public comment on whether we should limit the number of times this add-on code (HCPCS code GCCC2) can be reported in a given service period for a given beneficiary. It

is not clear how often more than 40 minutes of clinical staff time is currently spent or is medically necessary. In addition, once 60 minutes of clinical staff time is spent, many or most patients might also require complex medical decision-making, and such patients would be already described under existing coding for complex CCM. A limit (such as allowing the add-on code to be reported only once per service period per beneficiary) may be appropriate in order to maintain distinctions between complex and non-complex CCM, as well as appropriately limit beneficiary cost sharing and program spending to medically necessary services. We note that complex CCM already describes (in part) 60 or more minutes of clinical staff time in a service period. We are seeking comment on whether and how often beneficiaries who do not require complex CCM (for example, do not require the complex medical decision making that is part of complex CCM) would need 60 or more minutes of non-complex CCM clinical staff time and thereby warrant more than one use of HCPCS code GCCC2 within a service period.

b. Complex CCM Services (CPT Codes 99487 and 99489, and HCPCS Codes GCCC3 and GCCC4)

Currently, the CPT codes for complex CCM include in the code descriptors a requirement for establishment or substantial revision of the comprehensive care plan (see above). The code descriptors for complex CCM also include moderate to high complexity medical decision-making (moderate to high complexity medical decision-making is an explicit part of the services). We propose to adopt two new G codes that would be used for billing under the PFS instead of CPT codes 99487 and 99489, and that would not include the service component of substantial care plan revision. We believe it is not necessary to explicitly include substantial care plan revision because patients requiring moderate to high complexity medical decision making implicitly need and receive substantial care plan revision. The service component of substantial care plan revision is potentially duplicative with the medical decision making service component and, therefore, we believe it is unnecessary as a means of distinguishing eligible patients. Instead of CPT code 99487, we propose to adopt HCPCS code GCCC3 *(Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately)).* We are proposing a work RVU of 1.00 for HCPCS code GCCC3, which is a crosswalk to CPT code 99487.

Instead of CPT code 99489, we propose to adopt HCPCS code GCCC4 (*each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month)).* We are proposing a work RVU of 0.50 for HCPCS code GCCC4, which is a crosswalk to CPT code 99489.

We intend these would be temporary G codes to remain in place until the CPT Editorial Panel can consider revising the current code descriptors for complex CCM services. We would consider adopting any new or revised complex CCM CPT code(s) once the CPT Editorial Panel completes its work. We acknowledge that imposing a transitional period during which G codes would be used under the PFS in lieu of the CPT codes is potentially disruptive. We are seeking comment on whether the benefit of proceeding with the proposed G codes outweighs the burden of transitioning to their use in the intervening year(s) before a decision by the CPT Editorial Panel.

c. Typical Care Plan

In 2013, in working with the physician community to develop and propose the CCM codes for PFS payment, the medical community recommended and CMS agreed that adequate care planning is integral to managing patients with multiple chronic conditions. We stated our belief that furnishing care management to beneficiaries with multiple chronic conditions requires complex and multidisciplinary care modalities that involve, among other things, regular physician development and/or revision of care plans and integration of new information into the care plan (78 FR 43337). In the CY 2014 PFS final rule with comment period (78 FR 74416 through 74418), consistent with recommendations CMS received in 2013 from the AMA's Complex Chronic Care Coordination Workgroup, we finalized a CCM scope of service element for a patient-centered plan of care with the following characteristics: It is a comprehensive plan of care for all health problems and typically includes, but is not limited to, the following elements: Problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; community/social services ordered; how the services of agencies and specialists unconnected to the practice will be directed/coordinated; identify the individuals responsible for each intervention, requirements for periodic review; and when applicable, revisions of the care plan.

The CPT Editorial Panel also incorporated and adopted this language in the prefatory language for Care Management Services codes (page 49 of the 2019 CPT Codebook) including CCM services.

As we continue to consider the need for potential refinements to the CCM code set, we have heard that there is still some confusion in the medical community regarding what a care plan typically includes. We have re-reviewed this language for CCM, and we believe there may be aspects of the typical care plan language we adopted for CCM that are redundant or potentially unduly burdensome. We note that because these are ''typical'' care plan elements, these elements do not comprise a set of strict requirements that must be included in a care plan for purposes of billing for CCM services; the elements are intended to reflect those that are typically, but perhaps not always, included in a care plan as medically appropriate for a particular beneficiary. Nevertheless, we are proposing to eliminate the phrase ''community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention'' and insert the phrase ''interaction and coordination with outside resources and practitioners and providers.'' We believe simpler language would describe the important work of interacting and coordinating with resources external to the practice. While it is preferable, when feasible, to identify who is responsible for

interventions, it may be difficult to maintain an up-to-date listing of responsible individuals especially when they are outside of the practice, for example, when there is staff turnover or assignment changes.

Our proposed new language would read: The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements:

- Problem list.
- Expected outcome and prognosis.
- Measurable treatment goals.
- Cognitive and functional assessment.
- Symptom management.
- Planned interventions.
- Medical management.
- Environmental evaluation.
- Caregiver assessment.
- Interaction and coordination with outside resources and practitioners and providers.
- Requirements for periodic review.
- When applicable, revision of the care plan.

We welcome feedback on our proposal, including language that would best guide practitioners as they decide what to include in their comprehensive care plan for CCM recipients.

Additional information regarding the existing requirements for billing CCM, including links to prior rules, is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html*.

4. Principal Care Management (PCM) Services

A gap we identified in coding and payment for care management services is care management for patients with only one chronic condition. The current CCM codes require patients to have two or more chronic conditions. These codes are primarily billed by practitioners who are managing a patient's total care over a month, including primary care practitioners and some specialists such as cardiologists or nephrologists. We have heard from a number of stakeholders, especially those in specialties that use the office/outpatient E/M code set to report the majority of their services, that there can be significant resources involved in care management for a single high risk disease or complex chronic condition that is not well accounted for in existing coding (FR 78 74415). This issue has also been raised by the stakeholder community in proposal submissions to the Physician-Focused Payment Model Technical Advisory Committee (PTAC), which are available at *https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee*. Therefore, we are proposing separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition. A qualifying condition would typically be expected to last between three months and a year, or until the death of the patient, may have led to a recent hospitalization, and/or place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

While we are not proposing any restrictions on the specialties that could bill for PCM, we expect that most of these services would be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. We expect that, in most instances, initiation of PCM would be triggered by an exacerbation of the patient's complex chronic condition or recent hospitalization such that disease-specific care management is warranted. We anticipate that in the majority of instances, PCM services would be billed when a single condition is of such complexity that it could not be managed as effectively in the primary care setting, and instead requires management by another, more specialized, practitioner. For example, a typical patient may present to their primary care practitioner with an exacerbation of an existing chronic condition. While the primary care practitioner may be able to provide care management services for this one complex chronic condition, it is also possible that the primary care practitioner and/or the patient could instead decide that another clinician should provide relevant care management services. In this case, the primary care practitioner would still oversee the overall care for the patient while the practitioner billing for PCM services would provide care management services for the specific complex chronic condition. The treating clinician may need to provide a disease-specific care plan or may need to make frequent adjustments to the patient's medication regimen. The expected outcome of PCM is for the patient's condition to be stabilized by the treating clinician so that overall care management for the patient's condition can be returned to the patient's primary care practitioner. If the beneficiary only has one complex chronic condition that is overseen by the primary care practitioner, then the primary care practitioner would also be able to bill for PCM services. We are proposing that PCM services include coordination of medical and/or psychosocial care related to the single complex chronic condition, provided by a physician or clinical staff under the direction of a physician or other qualified health care professional.

We anticipate that many patients will have more than one complex chronic condition. If a clinician is providing PCM services for one complex chronic condition, management of the patient's other conditions would continue to be managed by the primary care practitioner while the patient is receiving PCM services for a single complex condition. It is also possible that the patient could receive PCM services from more than one clinician if the patient experiences an exacerbation of more than one complex chronic condition simultaneously.

For CY 2020, we are proposing to make separate payment for PCM services via two new G codes: HCPCS code GPPP1 (*Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities*) and HCPCS code GPPP2 (*Comprehensive care management for a single high-risk disease services, e.g., Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities*). HCPCS code GPPP1 would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care provider time is spent on comprehensive care management for a

single high risk disease or complex chronic condition. HCPCS code GPPP2 would be reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high risk disease or complex chronic condition.

For HCPCS code GPPP1, we are proposing a crosswalk to the work value associated with CPT code 99217 (*Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital* ''*observation status*'' *if the discharge is on other than the initial date of* ''*observation status.*'' *To report services to a patient designated as* ''*observation status*'' *or* ''*inpatient status*'' *and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234–99236 as appropriate]*)) as we believe these values most accurately reflect the resource costs associated when the billing practitioner performs PCM services. CPT code 99217 has the same intraservice time as HCPCS code GPPP1 and the physician work is of similar intensity. Therefore, we are proposing a work RVU of 1.28 for HCPCS code GPPP1.

For HCPCS code GPPP2 we are proposing a crosswalk to the work and PE inputs associated with CPT code 99490 (clinical staff non-complex CCM) as we believe these values reflect the resource costs associated with the clinician's direction of clinical staff who are performing the PCM services, and the intraservice times and intensity of the work for the two codes would be the same. Therefore, we are proposing a work RVU of 0.61 for HCPCS code GPPP2.

While we are proposing separate coding and payment for PCM services performed by clinical staff with the oversight of the billing professional and services furnished directly by the billing professional, we are seeking comment on whether both codes are necessary to appropriately describe and bill for PCM services. We note that we are basing this coding structure on the codes for CCM services with CPT code 99491 reflecting care management by the billing professional and CPT code 99490 reflecting care management by clinical staff directed by a physician or other qualified health care professional.

We acknowledge that we are concurrently proposing revisions for both complex and non-complex CCM services. Were we not to finalize the proposed changes for both complex and non-complex CCM services, we believe that the overall structure and description of the CCM services remain close enough to serve as a model for the coding structure and description of services for the proposed PCM services. We are seeking public comment on whether it would be appropriate to create an add-on code for additional time spent each month (similar to HCPCS code GCCC2 discussed above) when PCM services are furnished by clinical staff under the direction of the billing practitioner.

While we believe that PCM services describe a situation where a patient's condition is severe enough to require care management for a single complex chronic condition beyond what is described by CCM or performed in the primary care setting, we are concerned that a possible unintended consequence of making separate payment for care management for a single chronic condition is that a patient with multiple chronic conditions could have their care managed by multiple practitioners, each only billing for PCM, which could potentially result in fragmented patient care, overlaps in services, and duplicative services. While we are not proposing additional requirements for the proposed PCM services, we did consider alternatives such as requiring that the practitioner billing PCM must document ongoing communication with the patient's primary care practitioner to demonstrate that there is continuity of care between the specialist and primary care settings, or requiring that the patient have had a face-to-face visit with the practitioner billing PCM within the prior 30 days to demonstrate that they have an ongoing relationship. We are seeking comment on whether requirements such as these are necessary or appropriate, and whether there should be additional requirements to prevent potential care fragmentation or service duplication.

Due to the similarity between the description of the PCM and CCM services, both of which involve non-face-to-face care management services, we are proposing that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. We are seeking comment on whether there are required elements of CCM services that the public and stakeholders believe should not be applicable to PCM, and should be removed or altered. A high level summary of these requirements is available in Table 18 and available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf*. Both the initiating visit and the patient's verbal consent are necessary as not all patients who meet the criteria to receive separately billable PCM services may want to receive these services. The beneficiary should be educated as to what PCM services are and any cost sharing that may apply. Additionally, as practitioners have informed us that beneficiary cost sharing is a significant barrier to provision of other care management services, we are seeking comment on how best to educate practitioners and beneficiaries on the benefits of PCM services.

Additionally, we are proposing to add GPPP2 to the list of designated care management services for which we allow general supervision as described in our regulation at § 410.26(b)(5). Due to the potential for duplicative payment, we are proposing that PCM could not be billed by the same practitioner for the same patient concurrent with certain other care management services, such as CCM, behavioral health integration services, and monthly capitated ESRD payments. We are also proposing that PCM would not be billable by the same practitioner for the same patient during a surgical global period, as we believe those resource costs would already be included in the valuation of the global surgical code.

TABLE 18—CHRONIC CARE MANAGEMENT SERVICES SUMMARY

CCM Service Summary*
Verbal Consent: • Inform regarding availability of the service; that only one practitioner can bill per month; the right to stop services effective at the end of any service period; and that cost sharing applies (if no supplemental insurance). • Document that consent was obtained. Initiating Visit for New Patients (separately paid). Certified Electronic Health Record (EHR) Use: • Structured Recording of Core Patient Information Using Certified EHR (demographics, problem list, medications, allergies).

TABLE 18—CHRONIC CARE MANAGEMENT SERVICES SUMMARY—Continued

CCM Service Summary *
24/7 Access (“On Call” Service).
Designated Care Team Member.
Comprehensive Care Management:
• Systematic needs assessment (medical and psychosocial).
• Ensure receipt of preventive services.
• Medication reconciliation, management and oversight of self-management.
Comprehensive Electronic Care Plan:
• Plan is available timely within and outside the practice (can include fax).
• Copy of care plan to patient/caregiver (format not prescribed).
• Establish, implement, revise or monitor the plan.
Management of Care Transitions/Referrals (e.g., discharges, ED visit follow up, referrals):
• Create/exchange continuity of care document(s) timely (format not prescribed).
Home- and Community-Based Care Coordination:
• Coordinate with any home- and community-based clinical service providers, and document communication with them regarding psychosocial needs and functional deficits.
Enhanced Communication Opportunities:
• Offer asynchronous non-face-to-face methods other than telephone, such as secure email.

* All elements that are medically reasonable and necessary must be furnished during the month, but all elements do not necessarily apply every month. Consent need only be obtained once, and initiating visits are only for new patients or patients not seen within a year prior to initiation of CCM.

We are also seeking comment on any potential for duplicative payment between the proposed PCM services and other services, such as interprofessional consultation services (CPT codes 99446–99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*), CPT code 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), and CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*)) or remote patient monitoring (CPT code 99091 (*Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days*), CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*), and CPT code 99457 (*Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month*)).

5. Chronic Care Remote Physiologic Monitoring Services

Chronic Care remote physiologic monitoring (RPM) services involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan, and the managing of a patient under the treatment plan. The current CPT code 99457 is a treatment management code, billable after 20 minutes or more of clinical staff/physician/other qualified professional time with a patient in a calendar month.

In September 2018, the CPT Editorial Panel revised the CPT code structure for CPT code 99457 effective beginning in CY 2020. The new code structure retains CPT code 99457 as a base code that describes the first 20 minutes of the treatment management services, and uses a new add-on code to describe subsequent 20 minute intervals of the service. The new code descriptors for CY 2020 are: CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; initial 20 minutes*) and CPT code 994X0 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes*).

In considering the work RVUs for the new add-on CPT code 994X0, we first considered the value of its base code. We previously valued the base code at 0.61 work RVUs. Given the value of the base code, we do not agree with the RUC-recommended work RVU of 0.61 for the add-on code. Instead, we are proposing a work RVU of 0.50 for the add-on code. This value is supported by CPT code 88381 (*Microdissection (i.e., sample preparation of microscopically identified target); manual*), which has the same intraservice and total times of 20 minutes with an XXX global period and work RVU of 0.53, as well as the survey value at the 25th percentile. We are proposing the RUC-recommended direct PE inputs for CPT code 994X0.

Finally, we are proposing that RPM services reported with CPT codes 99457 and 994X0 may be furnished under general supervision rather than the currently required direct supervision. Because care management services include establishing, implementing, revising, or monitoring treatment plans, as well as providing support services, and because RPM services (that is, CPT codes 99457 and 994X0) include establishing, implementing, revising, and monitoring a specific treatment plan for a patient related to one or more chronic conditions that are monitored remotely, we believe that CPT codes 99457 and 994X0 should be included as designated care management services. Designated care management services can be furnished under general

supervision. Section 410.26(b)(5) of our regulations states that designated care management services can be furnished under the general supervision of the ''physician or other qualified health care professional (who is qualified by education, training, licensure/regulation and facility privileging)'' (see also 2019 CPT Codebook, page xii) when these services or supplies are provided incident to the services of a physician or other qualified healthcare professional. The physician or other qualified healthcare professional supervising the auxiliary personnel need not be the same individual treating the patient more broadly. However, only the supervising physician or other qualified healthcare professional may bill Medicare for incident to services.

6. Comment Solicitation on Consent for Communication Technology-Based Services

In the CY 2019 PFS Final Rule, CMS finalized separate payment for a number of services that could be furnished via telecommunications technology. Specifically, CMS finalized HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*)), HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*)), CPT codes 99446–99449 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional*), CPT code 99451 (*Interprofessional telephone/internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time*), and CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes*).

As discussed in that rule, (83 FR 59490–59491), while a few commenters suggested that it would be less burdensome to obtain a general consent for multiple services at once, we stipulated that verbal consent must be documented in the medical record for each service furnished so that the beneficiary is aware of any applicable cost sharing. This is similar to the requirements for other non-face-to-face care management services under the PFS.

We have continued to hear from stakeholders that requiring advance beneficiary consent for each of these services is burdensome. For HCPCS codes G2010 and G2012, stakeholders have stated that it is difficult and burdensome to obtain consent at the outset of each of what are meant to be brief check-in services. For CPT codes 99446–99449, 99451 and 99452, practitioners have informed us that it is particularly difficult for the consulting practitioner to obtain consent from a patient they have never seen. Given our longstanding goals to reduce burden and promote the use of communication technology-based services, we are seeking comment on whether a single advance beneficiary consent could be obtained for a number of communication technology-based services. During the consent process, the practitioner would make sure the beneficiary is aware that utilization of these services will result in a cost sharing obligation. We are seeking comment on the appropriate interval of time or number of services for which consent could be obtained, for example, for all these services furnished within a 6 month or one year period, or for a set number of services, after which a new consent would need to be obtained. We are also seeking comment on the potential program integrity concerns associated with allowing advance consent and how best to minimize those concerns.

7. Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

RHCs and FQHCs are paid for general care management services using HCPCS code G0511, which is an RHC and FQHC-specific G-code for 20 minutes or more of CCM services, complex CCM services, or general behavioral health services. Payment for this service is set at the average of the national, non-facility payment rates for CPT codes 99490, 99487, and 99484. We are proposing to use the non-facility payment rates for HCPCS codes GCCC1 and GCCC3 instead of the non-facility payment rates for CPT codes 99490 and 99487, respectively, if these changes are finalized for practitioners billing under the PFS. We note that we are not proposing any changes in the valuation of these codes. Upon finalization, the payment for HCPCS code G0511 would be set at the average of the national, non-facility payment rates for HCPCS codes GCCC1 and GCCC3 and CPT code 99484.

L. Coinsurance for Colorectal Cancer Screening Tests

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' are two of the recognized procedures. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include other tests or procedures in the definition, and modifications to the tests and procedures described under this subsection, ''with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.'' Section 1861(s)(2)(R) of the Act includes these colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes these colorectal cancer screening services within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount. As such, there is no beneficiary responsibility for coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at 42 CFR 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance.

In addition to screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (§ 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary, and who uses the results of the diagnostic test in the management of the patient's specific medical problem. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (normally 20 percent) associated with these services.

We define ''colorectal cancer screening tests'' in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current policies, we exclude from the definition of colorectal screening services colonoscopies and sigmoidoscopies that begin as a screening service, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening services is based upon separate provisions of the statute dealing with the detection of lesions or growths during procedures (62 FR 59048, 59082, October 31, 1997). Section 1834(d)(2)(D) of the Act provides that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, section 1834(d)(3)(D) of the Act that provides if, during the course of a screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

Because we interpret sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(ii) of the Act to require us to pay for these tests as diagnostic tests, rather than as screening tests, the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), would not apply to those diagnostic procedures. As such, beneficiaries are responsible for the usual coinsurance that applies to the services (20 or 25 percent of the cost of the services depending on the setting).

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, it did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Although public commenters encouraged the agency to also eliminate the coinsurance in these circumstances, the agency found that the statute did not provide for elimination of the coinsurance (75 FR 73170, 73431, November 29, 2010).

Beneficiaries have continued to contact us noting their ''surprise'' that a coinsurance (20 or 25 percent depending on the setting) applies when they expected to receive a colorectal screening procedure to which coinsurance does not apply, but instead received what Medicare considers to be a diagnostic procedure because polyps were discovered and removed. Similarly, physicians have also expressed concerns about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during what they expected to be a screening procedure to which coinsurance does not apply. Other stakeholders and some members of Congress have regularly expressed to us that they consider the agency's policy on coinsurance for colorectal screening procedures during which tissue is removed to be a misinterpretation of the law.

Over the years, we have released a wide variety of publicly available educational materials that explain the Medicare preventive services benefits as part of our overall outreach activities to Medicare beneficiaries. These materials contain a complete description of the Medicare preventive services benefits, including information on colorectal cancer screening, and also provide relevant details on the applicability of cost sharing. These materials can be found at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243319.html.* We believe that the information in these materials can be instrumental in continuing to educate physicians and beneficiaries about cost sharing obligations in order to mitigate instances of ''surprise'' billing. We invite comment on whether we should consider establishing a requirement that the physician who plans to furnish a colorectal cancer screening notify the patient in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply. We specifically invite comment on whether we should require the physician, or their staff, to provide a verbal notice with a notation in the medical record, or whether we should consider a different approach to informing patients of the copay implications, such as a written notice with standard language that we would require the physician, or their staff, to provide to patients prior to a colorectal cancer screening. We note that we would consider adopting such a requirement in the final rule in accordance with public comments. We also invite comment on what mechanism, if any, we should consider using to monitor compliance with a notification requirement if we decide to finalize one for CY 2020 or through future rulemaking.

M. Therapy Services

1. Repeal of the Therapy Caps and Limitation To Ensure Appropriate Therapy

a. Background

In the CY 2019 PFS proposed and final rules (83 FR 34850; 83 FR 59654 and 59661), we discussed the statutory requirements of section 50202 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018). Beginning January 1, 2018, section 50202 of the BBA of 2018 repealed the Medicare outpatient therapy caps and the therapy cap exceptions process, while retaining the cap amounts as limitations and requiring medical review to ensure that therapy services are furnished when appropriate. Section 50202 of the BBA of 2018 amended section 1833(g) of the Act by adding a new paragraph (7)(A) requiring that after expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier on claims. We implemented this provision by continuing to require use of the existing KX modifier. By using the KX modifier on the claim, the therapy supplier or provider is attesting that the services are medically necessary and that supportive justification is documented in the medical record. As with the incurred expenses for the prior therapy cap amounts, there is one amount for physical therapy (PT) and speech language pathology (SLP) services combined, and a separate amount for occupational therapy (OT) services. These KX modifier threshold amounts are indexed annually by the Medicare Economic Index (MEI). After the beneficiary's incurred expenditures for outpatient therapy services exceed the KX modifier threshold amount for the year, claims for outpatient therapy services without the KX modifier are denied.

Section 50202 of the BBA of 2018 also added a new paragraph 7(B) to section 1833(g) of the Act which retained the targeted medical review (MR) process for 2018 and subsequent years, but established a lower threshold amount of $3,000 rather than the $3,700 threshold amount that had applied for the original manual MR process established by section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) (Pub. L. 112–96, February 22, 2012). The manual MR process with a threshold amount of $3,700 was replaced by the targeted MR process with the same threshold amount through amendments made by section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015).

With the latest amendments made by the BBA of 2018, for CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), the MR threshold is $3,000 for PT and SLP services and $3,000 for OT services. For purposes of applying the targeted MR process, we use a criteria-based process for selecting providers and suppliers that includes factors such as a high percentage of patients receiving therapy beyond the medical review threshold as compared to peers. For information on the targeted medical review process, please visit *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html.*

In the CY 2019 PFS final rule (83 FR 59661), when discussing our tracking and accrual process for outpatient therapy services in the section on the KX Threshold Amounts, we noted that we track each beneficiary's incurred expenses for therapy services annually by applying the PFS-based payment amount for each service less any applicable multiple procedure reduction for CMS-designated ''always therapy'' services. We also stated that we use the PFS rates to accrue expenses for therapy services provided in critical access hospitals (CAHs) as required by section 1833(g)(6)(B) of the Act, added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, January 2, 2013). As discussed below, we mistakenly indicated that this statutory requirement was extended by subsequent legislation, including section 50202 of the BBA of 2018.

b. Proposed Regulatory Revisions

While we explained and implemented the changes required by section 50202 of the BBA of 2018 in CY 2019 PFS rulemaking (83 FR 34850; 83 FR 59654 and 59661), we did not codify those changes in regulation text. We are now proposing to revise the regulations at §§ 410.59 (outpatient occupational therapy) and 410.60 (physical therapy and speech-language pathology) to incorporate the changes made by section 50202 of the BBA of 2018. We propose to add a new paragraph (e)(1)(v) to §§ 410.59 and 410.60 to clarify that the specified amounts of annual per-beneficiary incurred expenses are no longer applied as limitations but as threshold amounts above which services require, as a condition of payment, inclusion of the KX modifier; and that use of the KX modifier confirms that the services are medically necessary as justified by appropriate documentation in the patient's medical record. We propose to amend paragraph (e)(2) in §§ 410.59 and 410.60 to specify the therapy services and amounts that are accrued for purposes of applying the KX modifier threshold, including the continued accrual of therapy services furnished by CAHs directly or under arrangements at the PFS-based payment rates. We are also proposing to amend paragraph (e)(3) in §§ 410.59 and 410.60 for the purpose of applying the medical review threshold to clarify the threshold amounts and the applicable years for both the manual MR process originally established through section 3005(g) of MCTRJCA and the targeted MR process established by the MACRA, and including the changes made through section 50202 of the BBA of 2018 as discussed previously.

In the CY 2019 PFS final rule (83 FR 59661), we incorrectly stated that section 1833(g)(6)(B) of the Act continues to require that we accrue expenses for therapy services furnished by CAHs at the PFS rate because the provision, originally added by section 603(b) of the ATRA, was extended by subsequent legislation, including section 50202 of the BBA of 2018. The requirement in section 1833(g)(6)(B) of the Act was actually time-limited to services furnished in CY 2013. To apply the therapy caps (and now the KX modifier thresholds) after the expiration of the requirement in 1833(g)(6)(B) of the Act, we needed a process to accrue the annual expenses for therapy services furnished by CAHs and, in the CY 2014 PFS final rule with comment period, we elected to continue the process prescribed in section 1833(g)(6)(B) of the Act (78 FR 74405 through 74410).

2. Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

a. Background

Section 53107 of the BBA of 2018 added a new subsection 1834(v) to the Act to require in paragraph (1) that, for services furnished on or after January 1, 2022, payment for outpatient physical and occupational therapy services for which payment is made under sections 1848 or 1834(k) of the Act which are furnished in whole or in part by a therapy assistant must be paid at 85 percent of the amount that is otherwise applicable. Section 1834(v)(2) of the Act further required that we establish a modifier to identify these services by January 1, 2019, and that claims for outpatient therapy services furnished in

whole or in part by a therapy assistant must include the modifier effective for dates of service beginning on January 1, 2020. Section 1834(v)(3) of the Act required that we implement the subsection through notice and comment rulemaking.

In the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852 and 83 FR 59654 through 50660, respectively), we established two modifiers—one to identify services furnished in whole or in part by a physical therapist assistant (PTA) and the other to identify services furnished in whole or in part by an occupational therapy assistant (OTA). The modifiers are defined as follows:

- *CQ Modifier:* Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant.
- *CO Modifier:* Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant.

In the CY 2019 PFS final rule, we clarified that the CQ and CO modifiers are required to be used when applicable for services furnished on or after January 1, 2020, on the claim line of the service alongside the respective GP or GO therapy modifier to identify services furnished under a PT or OT plan of care. The GP and GO therapy modifiers, along with the GN modifier for speech-language pathology (SLP) services, have been used since 1998 to track and accrue the per-beneficiary incurred expenses amounts to different therapy caps, now KX modifier thresholds, one amount for PT and SLP services combined and a separate amount for OT services. We also clarified in the CY 2019 PFS final rule that the CQ and CO modifiers will trigger application of the reduced payment rate for outpatient therapy services furnished in whole or in part by a PTA or OTA, beginning for services furnished in CY 2022.

In response to public comments on the CY 2019 PFS proposed rule, we did not finalize our proposed definition of ''furnished in whole or in part by a PTA or OTA'' as a service for which any minute of a therapeutic service is furnished by a PTA or OTA. Instead, we finalized a *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.

We also explained in the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852 and 83 FR 59654 through 59660, respectively) that the CQ and CO modifiers would not apply to claims for outpatient therapy services that are furnished by, or incident to the services of, physicians or nonphysician practitioners (NPPs) including nurse practitioners, physician assistants, and clinical nurse specialists. This is because our regulations for outpatient physical and occupational therapy services require that an individual furnishing outpatient therapy services incident to the services of a physician or NPP must meet the qualifications and standards for a therapist. As such, only therapists and not therapy assistants can furnish outpatient therapy services incident to the services of a physician or NPP (83 FR 59655 through 59656); and, the new PTA and OTA modifiers cannot be used on the line of service of the professional claim when the rendering NPI identified on the claim is a physician or an NPP. We also intend to revise our manual provisions at Pub. 100–02, Medicare Benefit Policy Manual (MBPM), Chapter 15, section 230, as appropriate, to reflect requirements for the new CQ and CO modifiers that will be used to identify services furnished in whole or in part by a PTA or OTA starting in CY 2020. We anticipate amending these manual provisions for CY 2020 to reflect the policies we adopt through the CY 2020 PFS notice and comment rulemaking process.

In PFS rulemaking for CY 2019, we identified certain situations when the therapy assistant modifiers do apply. The modifiers are applicable to:

- Therapeutic portions of outpatient therapy services furnished by PTAs/OTAs, as opposed to administrative or other non-therapeutic services that can be performed by others without the education and training of OTAs and PTAs.
- Services wholly furnished by PTAs or OTAs without physical or occupational therapists.
- Evaluative services that are furnished in part by PTAs/OTAs (keeping in mind that PTAs/OTAs are not recognized to wholly furnish PT and OT evaluation or re-evaluations).

We also identified some situations when the therapy assistant modifiers do not apply. They do not apply when:

- PTAs/OTAs furnish services that can be done by a technician or aide who does not have the training and education of a PTA/OTA.
- Therapists exclusively furnish services without the involvement of PTAs/OTAs.

Finally, we noted that we would be further addressing application of the modifiers for therapy assistant services and the 10 percent *de minimis* standard more specifically in PFS rulemaking for CY 2020, including how the modifiers are applied in different scenarios for different types of services.

b. Applying the CQ and CO Modifiers

CMS interprets the references in section 1834(v)(1) and (2) of the Act to outpatient physical therapy ''service'' and outpatient occupational therapy ''service'' to mean a specific procedure code that describes a PT or OT service. This interpretation makes sense because section 1834(v)(2) of the Act requires the use of a modifier to identify on each request for payment, or bill submitted for an outpatient therapy service furnished in whole or in part by a PTA/OTA. For purposes of billing, each outpatient therapy service is identified by a procedure code.

To apply the *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, we propose to make the 10 percent calculation based on the respective therapeutic minutes of time spent by the therapist and the PTA/OTA, rounded to the nearest whole minute. The minutes of time spent by a PTA/OTA furnishing a therapeutic service can overlap partially or completely with the time spent by a physical or occupational therapist furnishing the service. We propose that the total time for a service would be the total time spent by the therapist (whether independent of, or concurrent with, a PTA/OTA) plus any additional time spent by the PTA/OTA independently furnishing the therapeutic service. When deciding whether the therapy assistant modifiers apply, we propose that if the PTA/OTA participates in the service concurrently with the therapist for only a portion of the total time that the therapist delivers a service, the CQ/CO modifiers apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes spent by the therapist furnishing the service. If the PTA/OTA and the therapist each separately furnish portions of the same service, we propose that the CQ/CO modifiers would apply when the minutes furnished by the therapy assistant are greater than 10 percent of the total minutes—the sum of the minutes spent by the therapist and therapy assistant—for that service. We propose to apply the CQ/CO modifier policies to all services that would be billed with the respective GP or GO therapy modifier. We believe this is appropriate because it is the same way that CMS currently identifies physical therapy or occupational therapy services for purposes of accruing incurred expenses for the thresholds and targeted review process.

For purposes of deciding whether the 10 percent *de minimis* standard is exceeded, we offer two different ways to compute this. The first is to divide the PTA/OTA minutes by the total minutes for the service—which is (a) the therapist's total time when PTA/OTA minutes are furnished concurrently with the therapist, or (b) the sum of the PTA/OTA and therapist minutes when the PTA/OTA's services are furnished separately from the therapist; and then to multiply this number by 100 to calculate the percentage of the service that involves the PTA/OTA. We propose to round to the nearest whole number so that when this percentage is 11 percent or greater, the 10 percent *de minimis* standard is exceeded and the CQ/CO modifier is applied. The other method is simply to divide the total time for the service (as described above) by 10 to identify the 10 percent *de minimis* standard, and then to add one minute to identify the number of minutes of service by the PTA/OTA that would be needed to exceed the 10 percent standard. For example, where the total time of a service is 60 minutes, the 10 percent standard is six (6) minutes, and adding one minute yields seven (7) minutes. Once the PTA/OTA furnishes at least 7 minutes of the service, the CQ/CO modifier is required to be added to the claim for that service. As noted above, we propose to round the minutes and percentages of the service to the nearest whole integer. For example, when the total time for the service is 45 minutes, the 10 percent calculation would be 4.5 which would be rounded up to 5, and the PTA/OTA's contribution would need to meet or exceed 6 minutes before the CQ/CO modifier is required to be reported on the claim. See Table 19 for minutes needed to meet or exceed using the ''simple'' method with typical times for the total time of a therapy service.

TABLE 19—SIMPLE METHOD FOR DETERMINING WHEN CQ/CO MODIFIERS APPLY

Method Two: simple method to apply 10 percent de minimis standard			
Total Time * examples using typical service total times	Determine the 10 percent standard by dividing service Total Time by 10	Round 10 percent standard to next whole integer	PTA/OTA Minutes needed to exceed—apply CQ/CO
10	1.0	1.0	2.0
15	1.5	2.0	3.0
20	2.0	2.0	3.0
30	3.0	3.0	4.0
45	4.5	5.0	6.0
60	6.0	6.0	7.0
75	7.5	8.0	9.0

Total Time equals total therapist minutes plus any PTA/OTA independent minutes. Concurrent minutes: When PTA/OTA's minutes are furnished concurrently with the therapist, total time equals the total minutes of the therapist's service. Separate minutes: When PTA/OTA's minutes are furnished separately from the minutes furnished by the therapist, total time equals the sum of the minutes of the service furnished by the PT/OT plus the minutes of the service furnished separately by the PTA/OTA.

We want to clarify that the 10 percent *de minimis* standard, and therefore the CQ/CO modifiers, are not applicable to services in which the PTA/OTA did not participate. To the extent that the PTA/OTA and the physical therapist/occupational therapist (PT/OT) separately furnish different services that are described by procedure codes defined in 15-minute increments, billing examples and proposed policies are included below in Scenario Two.

As we indicated in the CY 2019 PFS final rule, we are addressing more specifically in this proposed rule the application of the 10 percent *de minimis* standard in various clinical scenarios to decide when the CQ/CO modifiers apply. We acknowledge that application of the 10 percent *de minimis* standard can work differently depending on the types of services and scenarios involving both the PTA/OTA and the PT/OT. Therapy services are typically furnished in multiple units of the same or different services on a given treatment day, which can include untimed services (not billable in multiple units) and timed services that are defined by codes described in 15-minute intervals. The majority of the untimed services that therapists bill for fall into three categories: (1) Evaluative procedures, (2) group therapy, and (3) supervised modalities. We discuss each of these in greater detail below. Only one (1) unit can be reported in the claim field labeled ''units'' for each procedure code representing an untimed service. The preponderance of therapy services, though, are billed using codes that are described in 15-minute increments. These services are typically furnished to a patient on a single day in multiple units of the same and/or different services. Under our current policy, the total number of units of one or more timed services that can be added to a claim depends on the total time for all the 15-minute timed codes that were delivered to a patient on a single date of service. We address our proposals for applying the CQ/CO modifiers using the 10 percent *de minimis* standard, along with applicable billing scenarios, by category below. In each of these scenarios, we assume that the PTA/OTA minutes are for therapeutic services.

- *Evaluations and re-evaluations: CPT codes 97161 through 97163 for physical therapy evaluations for low, moderate, and high complexity level, and CPT code 97164 for physical therapy re-evaluation; and CPT codes 97165 through 97167 for occupational therapy evaluations for low, moderate, and high complexity level, and CPT 97168 for occupational therapy re-evaluation.* These PT and OT evaluative procedures are untimed codes and cannot be billed in multiple units—one unit is billed on the claim. As discussed in CY 2019 PFS rulemaking (83 FR 35852 and 83 FR 59656) and noted above, PTAs/OTAs are not recognized to furnish evaluative or assessment services, but to the extent that they furnish a portion of an evaluation or re-evaluation (such as completing clinical labor tasks for each code) that exceeds the 10 percent *de minimis* standard, the appropriate therapy assistant modifier (CQ or CO) must be used on the claim. We note that it is possible for the PTA/OTA to furnish these minutes either concurrently or separately from the therapist. For example, when the PTA/OTA assists the PT/OT concurrently for a 5-minute portion of the 30 minutes that a PT or OT spent furnishing an evaluation (for example, CPT code 97162 for moderate complexity PT evaluation or CPT code 97165 for a low complexity OT evaluation—each have a typical therapist face-to-face time of 30

minutes), the respective CQ or CO modifier is applied to the service because the 5 minutes surpasses the 10 percent *de minimis* standard. In other words, 10 percent of 30 minutes is 3 minutes, and the CQ or CO modifier applies if the PTA/OTA furnishes more than 3 minutes, meaning at least 4 minutes, of the service. If the PTA/OTA separately furnishes a portion of the service that takes 5 minutes (for example, performing clinical labor tasks such as obtaining vital signs, providing self-assessment tool to the patient and verifying its completion), and then the PT/OT separately (without the PTA/OTA) furnishes a 30 minute face-to-face evaluative procedure—bringing the total time of the service to 35 minutes (the sum of the separate PTA/OTA minutes, that is, 5 minutes, plus the 30-minute therapist service), the CQ or CO modifier would be applied to the service because the 5 minutes of OTA/PTA time exceeds 10 percent of the 35 total minutes for the service. In other words, 10 percent of 35 minutes is 3.5 minutes which is rounded up to 4 minutes. The CQ or CO modifier would apply when the PTA/OTA furnishes 5 or more minutes of the service, as discussed above and referenced in Table 19.

• *Group Therapy: CPT code 97150 (requires constant attendance of therapist or assistant, or both).* CPT code 97150 describes a service furnished to a group of 2 or more patients. Like evaluative services, this code is an untimed service and cannot be billed in multiple units on the claim, so one unit of the service is billed for each patient in the group. For the group service, the CQ/CO modifier would apply when the PTA/OTA wholly furnishes the service without the therapist. The CQ/CO modifier would also apply when the total minutes of the service furnished by the PTA/OTA (whether concurrently with, or separately from, the therapist), exceed 10 percent of the total time, in minutes, of the group therapy service (that is, the total minutes of service spent by the therapist (with or without the PTA/OTA) plus any minutes spent by the PTA/OTA separately from the therapist). For example, the modifiers would apply when the PTA/OTA participates concurrently with the therapist for 5 minutes of a total group therapy service time of 40-minutes (based on the time of the therapist); or when the PTA/OTA separately furnishes 5 minutes of a total group time of 40 minutes (based on the sum of minutes of the PTA/OTA (5) and therapist (35)).

• *Supervised Modalities: CPT codes 97010 through 97028, and HCPCS codes G0281, G0183, and G0329.* Modalities, in general, are physical agents that are applied to body tissue in order to produce a therapeutic change through various forms of energy, including but not limited to thermal, acoustic, light, mechanical or electric. Supervised modalities, for example vasopneumatic devices, paraffin bath, and electrical stimulation (unattended), do not require the constant attendance of the therapist or supervised therapy assistant, unlike the modalities defined in 15-minute increments that are discussed in the below category. When a supervised modality, such as whirlpool (CPT code 97022), is provided without the direct contact of a PT/OT and/or PTA/OTA, that is, it is furnished entirely by a technician or aide, the service is not covered and cannot be billed to Medicare. Supervised modality services are untimed, so only one unit of the service can be billed regardless of the number of body areas that are treated. For example, when paraffin bath treatment is provided to both of the patient's hands, one unit of CPT code 97018 can be billed, not two. For supervised modalities, the CQ or CO modifier would apply to the service when the PTA/OTA fully furnishes all the minutes of the service, or when the minutes provided by the PTA or OTA exceed 10 percent of total minutes of the service. For example, the CQ/CO modifiers would apply when either (1) the PTA/OTA concurrently furnishes 2 minutes of a total 8-minute service by the therapist furnishing paraffin bath treatment (HCPCS code 97018) because 2 minutes is greater than 10 percent of 8 minutes (0.8 minute, or 1 minute after rounding); or (2) the PTA/OTA furnishes 3 minutes of the service separately from the therapist who furnishes 5 minutes of treatment for a total time of 8 minutes (total time equals the sum of the PT/OT minutes plus the separate PTA/OTA minutes) because 3 minutes is greater than 10 percent of 8 total minutes (0.8 minute rounded to 1 minute).

• *Services defined by 15-minute increments/units: These timed codes are included in the following current CPT code ranges: CPT codes 97032 through 97542—including the subset of codes for modalities in the series CPT codes 97032 through 97036; and, codes for procedures in the series CPT codes 97110–97542; CPT codes 97750–97755 for tests and measurements; and CPT codes: 97760–97763 for orthotic management and training and prosthetic training.* Based on CPT instructions for these codes, the therapist (or their supervised therapy assistant, as appropriate) is required to furnish the service directly in a one-on-one encounter with the patient, meaning they are treating only one patient during that time. Examples of modalities requiring one-on-one patient contact include electrical stimulation (attended), CPT code 97032, and ultrasound, CPT code 97035. Examples of procedures include therapeutic exercise, CPT code 97110, neuromuscular reeducation, CPT 97112, and gait training, CPT code 97116.

Our policy for reporting of service units with HCPCS codes for both untimed services and timed services (that is, only those therapy services defined in 15-minute increments) is explained in section 20.2 of Chapter 5 of the Medicare Claims Processing Manual (MCPM). To bill for services described by the timed codes (hereafter, those codes described per each 15-minutes) furnished to a patient on a date of service, the therapist or therapy assistant needs to first identify all timed services furnished to a patient on that day, and then total all the minutes of all those timed codes. Next, the therapist or therapy assistant needs to identify the total number of units of timed codes that can be reported on the claim for the physical or occupational therapy services for a patient in one treatment day. Once the number of billable units is identified, the therapist or therapy assistant assigns the appropriate number of unit(s) to each timed service code according to the total time spent furnishing each service. For example, to bill for one 15-minute unit of a timed code, the qualified professional (the therapist or therapy assistant) must furnish at least 8 minutes and up to 22 minutes of the service; to bill for 2 units, at least 23 minutes and up to 37 minutes, and to bill for 3 units, at least 38 minutes and up to 52 minutes. We note that these minute ranges are applicable when one service, or multiple services, defined by timed codes are furnished by the qualified professional on a treatment day. We understand that the therapy industry often refers to these billing conventions as the ''eight-minute rule.'' The idea is that when a therapist or therapy provider bills for one or more units of services that are described by timed codes, the therapist's direct, one-on-one patient contact time would average 15 minutes per unit. This idea is also the basis for the work values we have established for these timed codes. Our current policies for billing of timed codes and related documentation do not take into consideration whether a service is furnished ''in whole or in

part'' by a PTA/OTA, or otherwise address the application of the CQ/CO modifier when the 10 percent *de minimis* standard is exceeded, for those services in which both the PTA/OTA and the PT/OT work together to furnish a service or services.

To support the number of 15-minute timed units billed on a claim for each treatment day, we require that the total timed-code treatment time be documented in the medical record, and that the treatment note must document each timed service, whether or not it is billed, because the unbilled timed service(s) can impact billing. The minutes that each service is furnished can be, but are not required to be, documented. We also require that each untimed service be documented in the treatment note in order to support these services billed on the claim; and, that the total treatment time for each treatment day be documented—including minutes spent providing services represented by the timed codes (the total timed-code treatment time) and the untimed codes. To minimize burden, we are not proposing changes to these documentation requirements in this proposed rule.

Beginning January 1, 2020, in order to provide support for application of the CQ/CO modifier(s) to the claim as required by section 1834(v)(2)(B) of the Act and our proposed regulations at §§ 410.59(a)(4) and 410.60(a)(4), we propose to add a requirement that the treatment notes explain, via a short phrase or statement, the application or non-application of the CQ/CO modifier for each service furnished that day. We would include this documentation requirement in subsection in Chapter 15, MBPM, section 220.3.E on treatment notes. Because the CQ/CO modifiers also apply to untimed services, our proposal to revise our documentation requirement for the daily treatment note extends to those codes and services as well. For example, when PTAs/OTAs assist PTs/OTs to furnish services, the treatment note could state one of the following, as applicable: (a) ''Code 97110: CQ/CO modifier applied—PTA/OTA wholly furnished''; or, (b) ''Code 97150: CQ/CO modifier applied—PTA/OTA minutes = 15%''; or ''Code 97530: CQ/CP modifier not applied—PTA/OTA minutes less than 10% standard.'' For those therapy services furnished exclusively by therapists without the use of PTAs/OTA, the PT/OT could note one of the following: ''CQ/CO modifier NA'', or ''CQ/CO modifier NA—PT/OT fully furnished all services.'' Given that the minutes of service furnished by or with the PTA/OTA and the total time in minutes for each service (timed and untimed) are used to decide whether the CQ/CO modifier is applied to a service, we seek comment on whether it would be appropriate to require documentation of the minutes as part of the CQ/CO modifier explanation as a means to avoid possible additional burden associated with a contractor's medical review process conducted for these services. We are also interested in hearing from therapists and therapy providers about current burden associated with the medical review process based on our current policy that does not require the times for individual services to be documented. Based on comments received, if we were to adopt a policy to include documentation of the PTA/OTA minutes and total time (TT) minutes, the CQ/CO modifier explanation could read similar to the following: ''Code 97162 (TT = 30 minutes): CQ/CO modifier not applied—PTA/OTA minutes (3) did not exceed the 10 percent standard.''

To recap, under our proposed policy, therapists or therapy assistants would apply the therapy assistant modifiers to the timed codes by first following the usual process to identify all procedure codes for the 15-minute timed services furnished to a beneficiary on the date of service, add up all the minutes of the timed codes furnished to the beneficiary on the date of service, decide how many total units of timed services are billable for the beneficiary on the date of service (based on time ranges in the chart in the manual), and assign billable units to each billable procedure code. The therapist or therapy assistant would then need to decide for each billed procedure code whether or not the therapy assistant modifiers apply.

As previously explained, the CQ/CO modifier does not apply if all units of a procedure code were furnished entirely by the therapist; and, where all units of the procedure code were furnished entirely by the PTA/OTA, the appropriate CQ/CO modifier would apply. When some portion of the billed procedure code is furnished by the PTA/OTA, the therapist or therapy assistant would need to look at the total minutes for all the billed units of the service, and compare it to the minutes of the service furnished by the PTA/OTA as described above in order to decide whether the 10 percent *de minimis* standard is exceeded. If the minutes of the service furnished by the PTA/OTA are more than 10 percent of the total minutes of the service, the therapist or therapy assistant would assign the appropriate CQ or CO modifier. We would make clarifying technical changes to chapter 5, section 20.2 of the MCPM to reflect the policies adopted through in this rulemaking related to the application or non-application of the therapy assistant modifiers. We anticipate that we will add examples to illustrate when the applicable therapy assistant modifiers must be applied, similar to the examples provided below.

We are providing the following examples of clinical scenarios to illustrate how the 10 percent *de minimis* standard would be applied under our proposals when therapists and their assistants work together concurrently or separately to treat the same patient on the same day. These examples reflect how the therapist or therapy provider would decide whether the CQ or CO therapy assistant modifier should be included when billing for one or more service units of the 15-minute timed codes. In the following scenarios, ''PT'' is used to represent physical therapist and ''OT'' is used to refer to an occupational therapist for ease of reference; and, the services of the PTA/OTA are assumed to be therapeutic in nature, and not services that a technician or aide without the education and training of a PTA/OTA could provide.

- *Scenario One:* Where only one service, described by a single HCPCS code defined in 15-minute increments, is furnished in a treatment day:

(1) The PT/OT and PTA/OTA each separately, that is individually and exclusively, furnish minutes of the same therapeutic exercise service (HCPCS code 97110) in different time frames: The PT/OT furnishes 7 minutes and the PTA furnishes 7 minutes for a total of 14 minutes, one unit can be billed using the total time minute range of at least 8 minutes and up to 22 minutes.

Billing Example: One 15-minute unit of HCPCS code 97110 is reported on the claim with the CQ/CO modifier to signal that the time of the service furnished by the PTA/OTA (7 minutes) exceeded 10 percent of the 14-minute total service time (1.4 minutes rounded to 1 minute, so the modifier would apply if the PTA/OTA had furnished 2 or more minutes of the service).

(2) The PT/OT and PTA/OTA each separately, exclusive of the other, furnish minutes of the same therapeutic exercise service (HCPCS code 97110) in different time frames: The PT/OT furnishes 20 minutes and the PTA/OTA furnishes 25 minutes for a total of 45 minutes, three units can be billed using the total time minute range of at least 38 minutes and up to 52 minutes.

Billing Example: All three units of CPT code 97110 are reported on the claim with the corresponding CQ/CO modifier because the 25 minutes

furnished by the PTA/OTA exceeds 10 percent of the 45-minute total service time (4.5 minutes rounded to 5 minutes, so the modifier would apply if the PTA/OTA had furnished 6 or more minutes of the service).

(3) The PTA/OTA works concurrently with the respective PT/OT as a team to furnish the same neuromuscular reeducation service (HCPCS code 97112) for a 30-minute session, resulting in 2 billable units of the service (at least 23 minutes and up to 37 minutes).

Billing Example: Both units of HCPCS code 97112 are reported with the appropriate CQ or CO modifier because the service time furnished by the PTA/OTA (30 minutes) exceeded 10 percent of the 30-minute total service time (3 minutes, so the modifier would apply if the PTA/OTA had furnished 4 or more minutes of the service).

- *Scenario Two:* When services that are represented by different procedure codes are furnished. Follow our current policy to identify the procedure codes to bill and the units to bill for the service(s) provided for the most time. We propose that when the PT/OT and the PTA/OTA each independently furnish a service defined by a different procedure code for the same number of minutes, for example 10 minutes, for a total time of 20 minutes, qualifying for 1 unit to be billed (at least 8 minutes up to 23 minutes), the code for the service furnished by the PT/OT is selected to break the tie—one unit of that service would be billed without the CQ/CO modifier.

(1) When only one unit of a service can be billed (requires a minimum of 8 minutes but less than 23 minutes):

(a) The PT/OT independently furnishes 15 minutes of manual therapy (HCPCS code 97140) and the PTA/OTA independently furnishes 7 minutes of therapeutic exercise (HCPCS code 97110). One unit of HCPCS code 97140 can be billed (at least 8 minutes and up to 22 minutes).

Billing Example: One unit of HCPCS code 97140 is billed without the CQ/CO modifier because the PT/OT exclusively (without the PTA/OTA) furnished a full unit of a service defined by 15-minute time interval (current instructions require ''1'' unit to be reported). The 7 minutes of a different service delivered solely by the PTA/OTA do not result in a billable service. Both services, though, are documented in the medical record, noting which services were furnished by the PT/OT or PTA/OTA; and, the 7 minutes of HCPCS code 97110 would be included in the total minutes of timed codes that are considered when identifying the procedure codes and units of each that can be billed on the claim.

(b) If instead, the PT/OT independently furnished 7 minutes of CPT code 97140 and the PTA/OTA independently furnished a full 15-minutes of CPT code 97110, one unit of CPT code 97110 is billed and the CQ/CO modifier is applied; the 7 minutes of the PT/OT service (CPT code 97140) do not result in billable service, but all the minutes are documented and included in the total minutes of the timed codes that are considered when identifying the procedure codes and units of each that can be billed on the claim.

(c) If the PT/OT and PTA/OTA each independently furnish an equal number of minutes of CPT codes 97140 and 97110, respectively, that is less than the full 15-minute mark, and the total minutes of the timed codes qualify for billing one unit of a service, the code furnished by the PT/OT would be selected to break the tie and billed without a CQ/CO modifier because the PT/OT furnished that service independently of the PTA/OTA.

If instead the PT/OT furnishes an 8-minute service (CPT code 97140) and the PTA/OTA delivers a 13-minute service (CPT code 97110), one unit of the 13-minute PTA/OTA-delivered service (CPT code 97110) would be billed consistent with our current policy to bill the service with the greater time; and the service would be billed with a CQ/CO modifier because the PTA/OTA furnished the service independently.

(2) When two or more units can be billed (requires a minimum of 23 minutes), follow current instructions for billing procedure codes and units for each timed code.

(a) The PT/OT furnishes 20 minutes of neuromuscular reeducation (CPT code 97112) and the PTA/OTA furnishes 8 minutes of therapeutic exercise (CPT code 97110) for a total of 28 minutes, which permits two units of the timed codes to be billed (at least 23 minutes and up to 37 minutes).

Billing Example: Following our usual process for billing for the procedure codes and units based on services furnished with the most minutes, one unit of each procedure code would be billed—one unit of CPT code 97112 is billed without a CQ/CO modifier and one unit of CPT code 97110 is billed with a CQ/CO modifier. This is because, under our current policy, the two billable units of timed codes are allocated among procedure codes by assigning the first 15 minutes of service to code 97112 (the code with the highest number of minutes), which leaves another 13 minutes of timed services: 5 minutes of code 97112 (20 minus 15) and 8 minutes of code 97110. Since the 8 minutes of code 97110 is greater than the remaining 5 minutes of code 97112, the second billable unit of service would be assigned to 97110. The CQ/CO modifier would not apply to CPT code 97112 because the therapist furnished all minutes of that service independently. The CQ/CO modifier would apply to CPT code 97110 because the PTA/OTA furnished all minutes of that service independently.

(b) The PT/OT furnishes 32 minutes of neuromuscular reeducation (CPT code 97112), the PT/OT and the PTA/OTA each separately furnish 12 minutes and 14 minutes, respectively, of therapeutic exercise (CPT code 97110) for a total of 26 minutes, and the PTA/OTA independently furnishes 12 minutes of self-care (CPT code 97535) for a total of 70 minutes of timed code services, permitting five units to be billed (68–82 minutes). Under our current policy, the five billable units would be assigned as follows: Two units to CPT code 97112, two units to CPT code 97110, and one unit to CPT code 97535.

Billing Example: The two units of CPT code 97112 would be billed without a CQ/CO modifier because all 32 minutes of that service were furnished independently by the PT/OT. The two units of CPT code 97110 would be billed with the CQ/CO modifier because the PTA/OTA's 14 minutes of the service are greater than 10 percent of the 26 total minutes of the service (2.6 minutes which is rounded to 3 minutes, so the modifiers would apply if the PTA/OTA furnished 4 or more minutes of the service), and the one unit of CPT code 97535 would be billed with a CQ/CO modifier because the PTA/OTA independently furnished all minutes of that service.

(c) The PT/OT independently furnishes 12 minutes of neuromuscular reeducation activities (CPT code 97112) and the PTA/OTA independently furnishes 8 minutes of self-care activities (CPT code 97535) and 7 minutes of therapeutic exercise (CPT code 97110)—the total treatment time of 27 minutes allows for two units of service to be billed (at least 23 minutes and up to 37 minutes). Under our current policy, the two billable units would be assigned as follows: One unit of CPT code 97112 and one unit of CPT code 97535.

Billing Example: The one unit of HCPCS code 97112 would be billed without the CQ/CO modifier because it was furnished independently by the PT/OT; and, the one unit of CPT code 97535 is billed with the CQ/CO modifier because it was independently furnished

by the PTA/OTA. In this example, CPT code 97110 is not billable; however, the minutes for all three codes are documented and counted toward the total time of the timed code services furnished to the patient on the date of service.

(d) The PT/OT furnishes 15 minutes of each of two services described by CPT codes 97112 and 97535, and is assisted by the PTA/OTA who furnishes 3 minutes of each service concurrently with the PT/OT. The total time of 30 minutes allows two 15-minute units to be billed—one unit each of CPT code 97112 and CPT code 97535.

Billing Example: Both CPT codes 97112 and 97535 are billed with the applicable CQ/CO modifier because the time the PTA/OTA spent assisting the PT/OT for each service exceeds 10 percent of the 15-minute total time for each service (1.5 minutes which is rounded to 2 minutes, so that the modifiers apply if the PTA/OTA furnishes 3 or more minutes of the service).

c. Proposed Regulatory Provisions

In accordance with section 1834(v)(2)(B) of the Act, we are proposing to amend §§ 410.59(a)(4) and 410.60(a)(4) for outpatient physical and occupational therapy services, respectively, and § 410.105(d) for physical and occupational therapy services furnished by comprehensive outpatient rehabilitation facilities (CORFs) as authorized under section 1861(cc) of the Act, to establish as a condition of payment that claims for services furnished in whole or in part by an OTA or PTA must include a prescribed modifier; and that services will not be considered furnished in part by an OTA or PTA unless they exceed 10 percent of the total minutes for that service, beginning for services furnished on and after January 1, 2020. To implement section 1834(v)(1) of the Act, we are proposing to amend §§ 410.59(a)(4) and 410.60(a)(4) for outpatient physical and occupational therapy services, respectively, and at § 410.105(d) for physical and occupational therapy services furnished by CORFs to specify that claims from physical and occupational therapists in private practice paid under section 1848 of the Act and from providers paid under section 1834(k) of the Act for physical therapy and occupational therapy services that contain a therapy assistant modifier, are paid at 85 percent of the otherwise applicable payment amount for the service for dates of service on and after January 1, 2022. As specified in the CY 2019 PFS final rule, we also note that the CQ or CO modifier is to be applied alongside the corresponding GP or GO therapy modifier that is required on each claim line of service for physical therapy or occupational therapy services. Beginning for dates of service and after January 1, 2020, claims missing the corresponding GP or GO therapy modifier will be rejected/returned to the therapist or therapy provider so they can be corrected and resubmitted for processing.

As discussed in the CY 2019 PFS proposed and final rules (*see* 83 FR 35850 and 83 FR 59654), we established that the reduced payment rate under section 1834(v)(1) of the Act for the outpatient therapy services furnished in whole or in part by therapy assistants is not applicable to outpatient therapy services furnished by CAHs, for which payment is made under section 1834(g) of the Act. We would like to take this opportunity to clarify that we do not interpret section 1834(v) of the Act to apply to outpatient physical therapy or occupational therapy services furnished by CAHs, or by other providers for which payment for outpatient therapy services is not made under section 1834(k) of the Act based on the PFS rates.

N. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.E. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and reproposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes

within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the federal government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we propose those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that included the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (*see* the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for

a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time. In response to comments in the CY 2019 PFS final rule (83 FR 59515), we clarify that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the proposed valuation considered for specific codes. Table 20 contains a list of codes and descriptors for which we are proposing work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2019. The proposed work RVUs, work time and other payment information for all CY 2020 payable codes are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 21 details our proposed refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain proposed refinements that would be common across codes. Proposed refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note

that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also note that approximately half of the refinements listed in Table 21 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also note that the proposed direct PE inputs for CY 2020 are displayed in the CY 2020 direct PE input files, available on the CMS website under the downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the proposed CY 2020 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2020, we received invoices for several new supply and equipment items. Tables 22 and 23 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encouraged stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encouraged stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 22 and 23 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address proposed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the public use files for the PFS proposed and final rules for each year display the services subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2020 are available on the CMS website under downloads for the CY 2020 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

4. Proposed Valuation of Specific Codes for CY 2020

(1) Tissue Grafting Procedures (CPT Codes 15X00, 15X01, 15X02, 15X03, and 15X04)

CPT code 20926 (*Tissue grafts, other (e.g., paratenon, fat, dermis)*), was identified through a review of services with anomalous sites of service when compared to Medicare utilization data. The CPT Editorial Panel subsequently replaced CPT code 20926 with five codes in the Integumentary section to better describe tissue grafting procedures.

We are proposing the RUC-recommended work RVUs of 6.68 for CPT code 15X00 (*Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)*), 6.73 for CPT code 15X01 (*grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50cc or less injectate*), 2.50 for CPT code 15X02 (*grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50cc injectate, or part thereof (list separately in addition to code for primary procedure)*), 6.83 for CPT code 15X03 (*grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25cc or less injectate*), and 2.41 for CPT code 15X04 (*grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25cc injectate, or part thereof (list separately in addition to code for primary procedure)*).

We are proposing the RUC-recommended direct PE inputs for this code family without refinement.

(2) Drug Delivery Implant Procedures (CPT Codes 11981, 11982, 11983, 206X0, 206X1, 206X2, 206X3, 206X4, and 206X5)

CPT codes 11980–11983 were identified as potentially misvalued since the majority specialty found in recent claims data differs from the two specialties that originally surveyed the codes. The current valuation of CPT code 11980 (*Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)*) was reaffirmed by the RUC as the physician work had not changed since the last review. The CPT Editorial Panel revised the other three existing codes in the family and created six additional add-on codes to describe orthopaedic drug delivery. These codes were surveyed and reviewed for the October 2018 RUC meeting.

CPT code 11980 (*Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)*) with the current work value of 1.10 RVUs and 12 minutes of intraservice time, and 27 minutes of total time, was determined to be unchanged since last reviewed and was recommended by the RUC to be maintained. We concur. We also are not proposing any direct PE refinements to CPT code 11980. CPT code 11981 (*Insertion, non-biodegradable drug delivery implant*) has a current work RVU of 1.48, with 39 minutes of total physician time. The specialty society survey recommended a work RVU of 1.30, with 31 minutes of total physician time and 5 minutes of intraservice time. The RUC recommended a work RVU of 1.30 (25th percentile), with 30 minutes of total physician time and 5 minutes of intraservice time. For comparable reference CPT codes to CPT code 11981, the RUC and the survey respondents had selected CPT code 55876 (*Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple (work RVU = 1.73, 20 minutes intraservice time and 59 total minutes)*) and CPT code 57500 (*Biopsy of cervix,*

single or multiple, or local excision of lesion, with or without fulguration (separate procedure) (work RVU = 1.20, 15 minutes intraservice time and 29 total minutes)). The RUC further offers for comparison, CPT code 67515 (*Injection of medication or other substance into Tenon's capsule (work RVU = 1.40 (from CY 2018), 5 minutes intraservice time and 21 minutes total time*)), CPT code 12013 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.6 cm to 5.0 cm (work RVU = 1.22 and 27 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) (work RVU = 1.44 and 29 total minutes)*). In addition, we offer CPT code 67500 (*Injection of medication into cavity behind eye) (work RVU = 1.18 and 5 minutes intraservice time and 33 total minutes*) for reference. Given that the CPT code 11981 incurs a 23 percent reduction in the new total physician time and with reference to CPT code 67500, we are proposing a work RVU of 1.14, and accept the survey recommended 5 minutes for intraservice time and 30 minutes of total time. We are not proposing any direct PE refinements to CPT code 11981.

CPT code 11982 (*Removal, non-biodegradable drug delivery implant*) has a current work RVU of 1.78, with 44 minutes of total physician time. The specialty society survey recommended a work RVU of 1.70 RVU, with 10 minutes of intraservice time and 34 minutes of total physician time. The RUC also recommended a work RVU of 1.70, with 10 minutes of intraservice time and 33 minutes of total physician time. The RUC confirmed that removal (CPT code 11982), requires more intraservice time to perform than the insertion (CPT code 11981). For comparable reference codes to CPT code 11982, the RUC and the survey respondents had selected CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block) (work RVU = 1.90, 15 minutes intraservice time and 45 total minutes)*) and CPT code 12004 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 7.6 cm to 12.5 cm) (work RVU = 1.44, with 17 minutes intraservice time and 29 minutes total time)*). We offer CPT code 64486 (*Injections of local anesthetic for pain control and abdominal wall analgesia on one side) (work RVU = 1.27, 10 minutes intraservice time and 35 total minutes)*) for reference. Given that the CPT code 11982 incurs a 25 percent reduction in the new total physician time and with reference to CPT code 64486, we are proposing a work RVU of 1.34, and accept the RUC-recommended 10 minutes for intraservice time and 33 minutes of total time. We are not proposing any direct PE refinements to CPT code 11982.

CPT code 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*) has a current work RVU of 3.30, with 69 minutes of total physician time. The specialty society survey recommended a work RVU of 2.50 RVU, with 15 minutes of intraservice time and 41 minutes of total physician time. The RUC also recommended a work RVU of 2.10, with 15 minutes of intraservice time and 40 minutes of total physician time. The RUC confirmed that CPT code 11983 requires more intraservice time to perform than the insertion CPT code 11981. For comparable reference codes to CPT code 11983, the RUC and the survey respondents had selected CPT code 55700 (*Biopsy, prostate; needle or punch, single or multiple, any approach) (work RVU = 2.50, 15 minutes intraservice time and 35 total minutes)*), CPT code 54150 (*Circumcision, using clamp or other device with regional dorsal penile or ring block) (work RVU = 1.90, 15 minutes intraservice time and 45 total minutes)*) and CPT code 52281 (*Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female) (work RVU = 2.75 and 20 minutes intraservice time and 46 minutes total time)*). We offer CPT code 62324 (*Insertion of indwelling catheter and administration of substance into spinal canal of upper or middle back) (work RVU = 1.89, 15 minutes intraservice time and 43 total minutes)*) for reference. Given that the CPT code 11983 incurs a 42 percent reduction in new total physician time and with reference to CPT code 62324, we are proposing a work RVU of 1.91, and accept the RUC-recommended 15 minutes for intraservice time and 40 minutes of total time. We are not proposing any direct PE refinements to CPT code 11983.

The new proposed add-on CPT codes 206X0–206X5 are intended to be typically reported with CPT codes 11981–11983, with debridement or arthrotomy procedures done primarily by orthopedic surgeons. The specialty society's survey for CPT code 206X0 (*Manual preparation and insertion of drug delivery device(s), deep (e.g., subfascial)*) found a 2.00 work RVU value at the median and a 1.50 work RVU value at the 25th percentile, with 20 minutes of intraservice time and 30 minutes of total physician time, for the preparation of the antibiotic powder and cement, rolled into beads and threaded onto suture for insertion into the infected bone. The RUC recommended a work RVU of 1.50, with 20 minutes of intraservice time and 27 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof) (work RVU = 1.80, and 30 minutes intraservice time)*), CPT codes 64484 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level) (work RVU = 1.00 and 10 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation) (work RVU = 2.09 and 20 minutes intraservice time)*). Our review of similar add-on CPT codes yielded CPT code 64634 (*Destruction of upper or middle spinal facet joint nerves with imaging guidance) (work RVU = 1.32 and 20 minutes intraservice time)*). We are proposing for CPT code 206X0, a work RVU of 1.32, and accept the RUC-recommended 20 minutes of intraservice time and 20 minutes of total time.

The specialty society's survey for CPT code 206X1 (*Manual preparation and insertion of drug delivery device(s), intramedullary*) found a 3.25 work RVU value at the median and a 2.50 work RVU value at the 25th percentile, with 25 minutes of intraservice time and 38 minutes of total physician time, for the preparation of the ''antibiotic nail'' ready for insertion into the intramedullary canal with fluoroscopic guidance. The RUC recommended a work RVU of 2.50, with 25 minutes of intraservice time and 32 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof) (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (work*

RVU = 4.88 and 45 minutes intraservice time)), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We find that the reference CPT code 11047, with 30 minutes of intraservice time, is suitable, but we adjust our proposed work RVU of 1.70 to account for the 25 minutes, instead of our reference code's 30 minutes of intraservice time (and the 32 minutes of total time), for CPT code 206X1.

The specialty society's survey for CPT code 206X2 (*Manual preparation and insertion of drug delivery device(s), intra-articular*) found a 4.00 work RVU value at the median and a 2.60 work RVU value at the 25th percentile, with 30 minutes of intraservice time and 45 minutes of total physician time, for the preparation of the antibiotic cement inserted into a pre-fabricated silicone mold, when after setting up, will be cemented to the end of the bone (with the joint). The RUC recommended a work RVU of 2.60, with 30 minutes of intraservice time and 37 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 57267 (*Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (work RVU = 4.88 and 45 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 20 minutes intraservice time)*). We find that the reference CPT code 11047, with 30 minutes of intraservice time, is a suitable guide and we are proposing the work RVU of 1.80 with the RUC-recommended 30 minutes of intraservice time and 37 minutes of total time, for CPT code 206X2.

The specialty society's survey for CPT code 206X3 (*Removal of drug delivery device(s), deep (e.g., subfascial)*) found a 1.75 work RVU value at the median and a 1.13 work RVU value at the 25th percentile, with 15 minutes of intraservice time and 18 minutes of total physician time. The work includes a marginal dissection to expose the drug delivery device and to remove it. The RUC recommended a work RVU of 1.13, with 18 minutes of total physician time and 15 minutes of intraservice time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 64484 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (work RVU = 1.00 and 10 minutes intraservice time)*), and CPT code 64480 (*Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (work RVU = 1.20 and 15 minutes intraservice time)*). We are proposing the RUC-recommended work RVU of 1.13 with 15 minutes of intraservice time and 18 minutes of total time for 206X3.

The specialty society's survey for CPT code 206X4 (*Removal of drug delivery device(s), intramedullary*) found a 2.50 work RVU value at the median and a 1.80 work RVU value at the 25th percentile, with 20 minutes of intraservice time and 28 minutes of total physician time. The work includes a marginal dissection, in addition to what was in the base procedure, to loosen and expose the drug delivery device and to remove it, any remaining drug delivery device shards that may have broken off. The RUC recommended a work RVU of 1.80, with 20 minutes of intraservice time and 23 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT codes 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (work RVU = 1.44 and 20 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We are proposing the RUC-recommended work RVU of 1.80 with 20 minutes of intraservice time and 23 minutes of total time for 206X4.

The specialty society's survey for CPT code 206X5 (*Removal of drug delivery device(s), intra-articular*) found a 3.30 work RVU value at the median and a 2.15 work RVU value at the 25th percentile, with 25 minutes of intraservice time and 28 minutes of total physician time. The work includes the removal of the intra-articular drug delivery device that is cemented to both sides of the joint without removing too much bone in the process. The RUC recommended a work RVU of 2.15, with 25 minutes of intraservice time and 28 minutes of total physician time. The RUC's reference CPT codes included CPT code 11047 (*Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (work RVU = 1.80, and 30 minutes intraservice time)*), CPT code 36476 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites (work RVU = 2.65 and 30 minutes intraservice time)*), and CPT code 36227 (*Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (work RVU = 2.09 and 15 minutes intraservice time)*). We are proposing the RUC-recommended work RVU of 2.15 with 25 minutes of intraservice time and 28 minutes of total time for 206X5.

(3) Bone Biopsy Trocar-Needle (CPT Codes 20220 and 20225)

In October 2017, CPT code 20225 (*Biopsy, bone, trocar, or needle; deep (e.g., vertebral body, femur)*) was identified as being performed by a different specialty than the one that originally surveyed this service. CPT code 20220 (*Biopsy, bone, trocar, or needle; superficial (e.g., ilium, sternum, spinous process, ribs)*) was added as part of the family, and both codes were surveyed and reviewed for the January 2019 RUC meeting.

We disagree with the RUC-recommended work RVU of 1.93 for CPT code 20220 and we are proposing a work RVU of 1.65 based on a crosswalk to CPT code 47000 (*Biopsy of liver, needle; percutaneous*). CPT code 47000 shares the same intraservice time of 20 minutes with CPT code 20220 and has slightly higher total time at 55 minutes as compared to 50 minutes. It

is also one of the top reference codes selected by the survey respondents. In our review of CPT code 20220, we noted that the recommended intraservice time is decreasing from 22 minutes to 20 minutes (9 percent reduction), and that the recommended total time is increasing from 49 minutes to 50 minutes (2 percent increase). However, the RUC-recommended work RVU is increasing from 1.27 to 1.93, which is an increase of 52 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, changes in surveyed work time should be appropriately reflected in the proposed work RVUs.

In the case of CPT code 20220, we believe that it would be more accurate to propose a work RVU of 1.65, based on a crosswalk to CPT code 47000, to account for the decrease in the surveyed intraservice work time. We believe that the work carried out by the practitioner in CPT code 47000 is potentially more intense than the work performed in CPT code 20220, as the reviewed code is a superficial bone biopsy as opposed to the non-superficial biopsy taking place on an internal organ (the liver) described by CPT code 47000. We also note that the survey respondents considered CPT code 47000 to have similar intensity to CPT code 20220: 50 percent or more of the survey respondents rated the two codes as ''identical'' under the categories of Mental Effort and Judgment, Physical Effort Required, and Psychological Stress, along with a plurality of survey respondents rating the two codes as identical in the category of Technical Skill Required. We believe that this provides further support for our belief that CPT code 20220 should be crosswalked to CPT code 47000 at the same work RVU of 1.65.

We disagree with the RUC-recommended work RVU of 3.00 for CPT code 20225 and we are proposing a work RVU of 2.45 based on a crosswalk to CPT code 30906 (*Control nasal hemorrhage, posterior, with posterior nasal packs and/or cautery, any method; subsequent*). CPT code 30906 shares the same intraservice time of 30 minutes and has 1 fewer minute of total time as compared to CPT code 20225. When reviewing this code, we observed a pattern similar to what we had seen with CPT code 20220. We note that the recommended intraservice time for CPT code 20225 is decreasing from 60 minutes to 30 minutes (50 percent reduction), and the recommended total time is decreasing from 135 minutes to 64 minutes (53 percent reduction); however, the RUC-recommended work RVU is increasing from 1.87 to 3.00, which is an increase of about 60 percent. As we noted earlier, we do not believe that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, and we are not proposing a linear decrease in the work valuation based on these time ratios. Indeed, we agree with the RUC recommendation that the work RVU of CPT code 20225 should increase over the current valuation. However, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in changes to the work RVUs, and we do not believe that it would be accurate to propose the recommended work RVU of 3.00 given the significant decreases in surveyed work time.

Instead, we believe that it would be more accurate to propose a work RVU of 2.45 for CPT code 20225 based on a crosswalk to CPT code 30906. We note that this proposed work RVU is a very close match to the intraservice time ratio between the two codes in the family; we are proposing a work RVU of 1.65 for CPT code 20220 with 20 minutes of intraservice work time, and a work RVU of 2.45 for CPT code 20225 with 30 minutes of intraservice work time. (The exact intraservice time ratio calculates to a work RVU of 2.47.) We believe that the proposed work RVUs maintain the relative intensity of the two codes in the family, and better preserve relativity with the rest of the codes on the PFS.

For the direct PE inputs, we are proposing to replace the bone biopsy device (SF055) supply with the bone biopsy needle (SC077) in CPT code 20225. We note that this code currently makes use of the bone biopsy needle, and there was no rationale provided in the recommended materials to explain why it would now be typical for the bone biopsy needle to be replaced by the bone biopsy device. We are proposing to maintain the use of the current supply item. We are also proposing to adopt a 90 percent utilization rate for the use of the CT room (EL007) equipment in CPT code 20225. We previously finalized a policy in the CY 2010 PFS final rule (74 FR 61754 through 61755) to increase the equipment utilization rate to 90 percent for expensive diagnostic equipment priced at more than $1 million, and specifically cited the use of CT and MRI equipment which would be subject to this utilization rate.

(4) Trigger Point Dry Needling (CPT Codes 205X1 and 205X2)

For CY 2020, the CPT Editorial Panel approved two new codes to report dry needling of musculature trigger points. These codes were surveyed and reviewed by the HCPAC for the January 2019 RUC meeting.

We disagree with the HCPAC-recommended work RVU of 0.45 for CPT code 205X1 (*Needle insertion(s) without injection(s), 1 or 2 muscle(s)*) and we are proposing a work RVU of 0.32 based on a crosswalk to CPT code 36600 (*Arterial puncture, withdrawal of blood for diagnosis*). CPT code 36600 shares the identical intraservice time, total time, and intensity with CPT code 205X1, which makes it an appropriate choice for a crosswalk. In our review of CPT code 205X1, we compared the procedure to the top reference code chosen by the survey participants, CPT code 97140 (*Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes*). This therapy procedure has 50 percent more intraservice time than CPT code 205X1, as well as higher total time; however, the recommended work RVU of 0.45 was higher than the work RVU of 0.43 for the top reference code from the survey. We did not agree that CPT code 205X1 should be valued at a higher rate, and therefore, we are proposing a work RVU of 0.32 based on the aforementioned crosswalk to CPT code 36600.

We disagree with the HCPAC-recommended work RVU of 0.60 for CPT code 205X2 (*Needle insertion(s) without injection(s), 3 or more muscle(s)*) and we are proposing a work RVU of 0.48 based on a crosswalk to CPT codes 97113 (*Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises*) and 97542 (*Wheelchair management (e.g., assessment, fitting, training), each 15 minutes*). Both of these codes share the same work RVU of 0.48 and the same intraservice time of 15 minutes as CPT code 205X2, with CPT code 97113 having two fewer minutes of total time and CPT code 97542 having two additional minutes of total time. We note that this proposed work RVU is an exact match of the intraservice time ratio between the two codes in the family; we are proposing a work RVU of 0.32 for CPT code 205X1 with 10 minutes of intraservice work time, and a work RVU of 0.48 for CPT code 205X2 with 15 minutes of intraservice work time. We also considered crosswalking the work RVU of CPT code 205X2 to the

top reference code from the survey, CPT code 97140, at a work RVU of 0.43. However, we chose to employ the crosswalk to CPT codes 97113 and 97542 at a work RVU of 0.48 instead, due to the fact that the survey respondents indicated that CPT code 205X2 was more intense than CPT code 97140.

We are also proposing to designate CPT codes 205X1 and 205X2 as ''always therapy'' procedures, and we are soliciting comments on this designation. We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(5) Closed Treatment Vertebral Fracture (CPT Code 22310)

This service was identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes.

For CPT code 22310 (*Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing*), we disagree with the recommended work RVU of 3.75 because we do not believe that this reduction in work RVU from the current value of 3.89 is commensurate with the RUC-recommended a 33-minute reduction in intraservice time and a 105-minute reduction in total time. While we understand that the RUC considers the current Harvard study time values for this service to be invalid estimations, we believe that a further reduction in work RVUs is warranted given the significance of the RUC-recommended reduction in physician time. We believe that it would be more accurate to propose a work RVU of 3.45 with a crosswalk to CPT code 21073 (*Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care)*), which has an identical intraservice time and similar total time as those proposed by the RUC for CPT code 22310, as we believe that this better accounts for the decrease in the surveyed work time.

For the direct PE inputs, we are proposing to refine the equipment time for the power table (EF031) to conform to our established standard for non-highly technical equipment.

(6) Tendon Sheath Procedures (CPT Codes 26020, 26055, and 26160)

The RUC identified these services through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 26020 (Drainage of tendon sheath, digit and/or palm, each), we do not agree with the RUC-recommended work RVU of 7.79 based on the survey median. While we agree that the survey data validate an increase in work RVU, we see no compelling reason that this service would be significantly more intense to furnish than services of similar time values. Therefore, we are proposing a work RVU of 6.84 which is the survey 25th percentile. As further support for this value, we note that it falls between the work RVUs of CPT code 28122 *(Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus*), with a work RVU of 6.76, and CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*), with a work RVU of 6.90; both codes have intraservice time values that are identical to, and total time values that are similar to, the RUC-recommended time values for CPT code 26020.

For CPT code 26055 (*Tendon sheath incision (e.g., for trigger finger)*), we do not agree with the RUC recommendation to increase the work RVU to 3.75 despite a reduction in physician time. Instead, we are proposing to maintain the current work RVU of 3.11; we are supporting this based on a total time increment methodology between the CPT code 26020 and CPT code 26055. The total time ratio between the recommended time of 119 minutes and the recommended 262 minutes for code 26020 equals 45 percent, and 45 percent of our proposed RVU of 6.84 for CPT code 26020 equals a work RVU of 3.10, which we believe validates the current work RVU of 3.11. We are proposing the RUC-recommended work RVU of 3.57 for CPT code 26160 (*Excision of lesion of tendon sheath or joint capsule (e.g., cyst, mucous cyst, or ganglion), hand or finger*). We note that our proposed work RVUs validate the RUC's contention that CPT code 26160 is slightly more intense to perform than CPT code 26055.

For the direct PE inputs, we are proposing to refine the quantity of the impervious staff gown (SB027) supply from 2 to 1 for CPT codes 26055 and 26160. We believe that the second impervious staff gown supply is duplicative due to the inclusion of this same supply in the surgical cleaning pack (SA043). The recommended materials state that a gown is worn by the practitioner and one assistant, which are provided by one standalone gown and a second gown in the surgical cleaning pack.

(7) Closed Treatment Fracture—Hip (CPT Code 27220)

This service was identified through a screen of services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. For CPT code 27220 (*Closed treatment of acetabulum (hip socket) fracture(s); without manipulation*), we disagree with the RUC-recommended work RVU of 6.00 based on the survey median value, because we do not believe that this reduction in work RVU from the current value of 6.83 is commensurate with the RUC-recommended a 19-minute reduction in intraservice time and an 80-minute reduction in total time. While we understand that the RUC considers the current Harvard study time values for this service to be invalid estimations, we believe that a further reduction in work RVUs is warranted given the significance of the RUC-recommended reduction in physician time. We believe that it would be more accurate to propose the survey 25th percentile work RVU of 5.50, and we are supporting this value with a crosswalk to CPT code 27267 (*Closed treatment of femoral fracture, proximal end, head; without manipulation*) to account for the decrease in the surveyed work time.

For the direct PE inputs, we are proposing to refine the equipment time for the power table (EF031) to conform to our established standard for non-highly technical equipment.

(8) Arthrodesis—Sacroliliac Joint (CPT Code 27279)

In the CY 2018 PFS final rule (82 FR 53017), CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device*) was nominated for review by stakeholders as a potentially misvalued service. We stated that CPT code 27279 is potentially misvalued, and that a comprehensive review of the code values was warranted. This code was subsequently reviewed by the RUC. According to the specialty societies, the previous 2014 survey of CPT code 27279, was based on flawed methodology that resulted in an underestimation of intraoperative intensity. When CPT code 27279 was surveyed in 2014, there was a low rate of response. Due to the dearth of survey data and the RUC's agreement with the specialty society at the time that the

survey respondents had somewhat overvalued the work involved in performing this service, the RUC used a crosswalk to CPT code 62287 (*Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar*) to recommend a work RVU of 9.03. The specialty societies indicated that with increased and broader utilization of this technique, the 2018 survey is a more robust assessment of physician work and intensity and provides more data with which to make a crosswalk recommendation. According to the RUC, there is no compelling evidence that the physician work, intensity or complexity has changed for this service.

We are proposing to maintain the current work RVU of 9.03 as recommended by the RUC. A stakeholder stated that maintaining this RVU would constitute the continued undervaluation of this service, and that this would incentivize use of a more intensive and invasive procedure, CPT code 27280 (*Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed*), as well as incentivize this service to be inappropriately furnished on an inpatient basis. This stakeholder has requested that, in the interest of protecting patient access, we implement payment parity between the two services by proposing to crosswalk the work RVU of CPT code 27279 to that of CPT code 27280, which has a work RVU of 20.00. While we are proposing the RUC-recommended work RVU, we are soliciting public comment on whether an alternative valuation of 20.00 would be more appropriate. This alternative valuation would recognize relative parity between these two services in terms of the work inherent in furnishing them.

We are proposing the RUC-recommended direct PE inputs for CPT code 27279.

(9) Pericardiocentesis and Pericardial Drainage (CPT Code 3X000, 3X001, 3X002, and 3X003)

CPT code 33015 (*Tube pericardiostomy*) was identified as potentially misvalued on a Relativity Assessment Workgroup (RAW) screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. In September 2018, the CPT Editorial Panel deleted four existing codes and created four new codes to describe periodcardiocentesis drainage procedures to differentiate by age and to include imaging guidance.

We are proposing to refine the work RVU for all four codes in the family. We disagree with the RUC-recommended work RVU of 5.00 for CPT code 3X000 (*Pericardiocentesis, including imaging guidance, when performed*) and are proposing a work RVU of 4.40 based on a crosswalk to CPT code 43244 (*Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices*). CPT code 43244 shares the same intraservice time of 30 minutes with CPT code 3X000 and has a slightly longer total time of 81 minutes as compared to 75 minutes for the reviewed code. In our review of CPT code 3X000, we noted that the recommended intraservice time as compared to the current initial pericardiocentesis procedure (CPT code 33010) is increasing from 24 minutes to 30 minutes (25 percent), and the recommended total time is remaining the same at 75 minutes; however, the RUC-recommended work RVU is increasing from 1.99 to 5.00, which is an increase of 151 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected with a commensurate increase the work RVUs. We also conducted a search in the RUC database among 0-day global codes with 30 minutes of intraservice time and comparable total time of 65–85 minutes. Our search identified 49 codes and all 49 of these codes had a work RVU lower than 5.00. We do not believe that it would serve the interests of relativity to establish a new maximum work RVU for this range of time values.

As a result, we believe that it is more accurate to propose a work RVU of 4.40 for CPT code 3X000 based on a crosswalk to CPT code 43244 to account for these modest increases in the surveyed work time as compared to the predecessor pericardiocentesis codes. We are aware that CPT code 3X000 is bundling imaging guidance into the new procedure, which was not included in the previous pericardiocentesis codes. However, we do not believe that the recoding of the services in this family has resulted in an increase in their intensity, only a change in the way in which they will be reported, and therefore, we do not believe that it would serve the interests of relativity to propose the RUC-recommended work values for all of the codes in this family. We also note that, through the bundling of some of these frequently reported services, it is reasonable to expect that the new coding system will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. For example, a practitioner would not be carrying out the full preservice work twice for CPT codes 33010 and 76930, but preservice times were assigned to both codes under the old coding. We believe the new coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that existed but were not reflected in the services as they were previously reported. If the addition of imaging guidance had made the new CPT codes significantly more intense to perform, we believe that this would have been reflected in the surveyed work times, which were largely unchanged from the predecessor codes.

We disagree with the RUC-recommended work RVU of 5.50 for CPT code 3X001 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly*) and are proposing a work RVU of 4.62 based on a crosswalk to CPT code 52234 (*Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 up to 2.0 cm)*). CPT code 52234 shares the same intraservice time of 30 minutes with CPT code 3X001 and has 2 additional minutes of total time at 79 minutes as compared to 77 minutes for the reviewed code. In our review of CPT code 3X001, we noted many of the same issues that we had raised with CPT code 3X000, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. We searched the RUC database again for 0-day global codes with 30 minutes of intraservice time and comparable total time of 67–87 minutes. Our search identified 43 codes and again all 43 of these codes had a work RVU lower than 5.50. As we stated with regard to CPT code 3X000, we do not believe that it would serve the interests of relativity to establish a new maximum work RVU for this range of time values. We believe that it is more accurate to propose a work RVU of 4.62 for CPT code 3X001 based on a crosswalk to CPT code 52234 based on the same rationale that we

detailed with regards to CPT code 3X000.

We disagree with the RUC-recommended work RVU of 6.00 for CPT code 3X002 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age, or any age with congenital cardiac anomaly*) and are proposing a work RVU of 5.00 based on the survey 25th percentile value. In our review of CPT code 3X002, we noted many of the same issues that we had raised with CPT codes 3X000 and 3X001, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. The recommended work RVU of 6.00 was based on a crosswalk to CPT code 31603 (*Tracheostomy, emergency procedure; transtracheal*), which shares the same intraservice time of 30 minutes with CPT code 3X002 and very similar total time. While we agree that CPT code 31603 is a close match to the surveyed work times for CPT code 3X002, we do not believe that it is the most accurate choice for a crosswalk due to the fact that CPT code 31603 is a clear outlier in work valuation. We searched for 0-day global codes in the RUC database with 30 minutes of intraservice time and a comparable 90–120 minutes of total time. There were 21 codes that met this criteria, and the recommended crosswalk to CPT code 31603 had the highest work RVU of any of these codes at the recommended 6.00. Furthermore, there was only one other code with a work RVU above 5.00, another tracheostomy procedure described by CPT code 31600 (Tracheostomy, planned (separate procedure)) at a work RVU of 5.56. None of the other codes had a work RVU higher than 4.69, and the median work RVU of the group comes out to only 4.00. The two tracheostomy procedures have work RVUs more than a full standard deviation above any of the other codes in this group of 0-day global procedures.

We do not mean to suggest that the work RVU for a given service must always fall in the middle of a range of codes with similar time values. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. However, we also do not believe that it would serve the interests of relativity by crosswalking the work RVU of CPT code 3X002 to tracheostomy procedures that are higher than anything else in this group of codes, procedures that we believe to be outliers due to the serious risk of patient mortality associated with their performance. We believe that it is this patient risk which is responsible for the otherwise anomalously high intensity in CPT codes 31600 and 31603. Therefore, we are proposing a work RVU of 5.00 for CPT code 3X002 based on the survey 25th percentile, which we believe more accurately captures both the time and intensity associated with the procedure.

We disagree with the RUC-recommended work RVU of 5.00 for CPT code 3X003 (*Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance*) and are proposing a work RVU of 4.29 based on the survey 25th percentile value. In our review of CPT code 3X003, we noted many of the same issues that we had raised with CPT codes 3X000–3X002, in particular with the increase in the work RVU greatly exceeding the increase in the surveyed work times as compared to the predecessor pericardiocentesis codes. We searched for 0-day global codes in the RUC database with 30 minutes of intraservice time (slightly higher than the 28 minutes of intraservice time in CPT code 3X003) and a comparable 70–100 minutes of total time. Our search identified 45 codes and again all 45 of these codes had a work RVU lower than 5.00, which led us to believe that the recommended work RVU for CPT code 3X003 was overvalued. We also compared CPT code 3X003 to the most similar code in the family, CPT code 3X001, and noted that the survey respondents indicated that CPT code 3X003 should have a lower work RVU at both the survey 25th percentile and survey median values. Therefore, we are proposing a work RVU of 4.29 for CPT code 3X003 based on the survey 25th percentile value. We are supporting this proposal with a reference to CPT code 31254 (*Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)*), a recently-reviewed code with an intraservice work time of 30 minutes, a total time of 84 minutes, and a work RVU of 4.27.

The RUC did not recommend and we are not proposing any direct PE inputs for the codes in this family.

(10) Pericardiotomy (CPT Codes 33020 and 33025)

CPT code 33020 (*Pericardiotomy for removal of clot or foreign body (primary procedure)*) was identified as potentially misvalued on a Relativity Assessment Workgroup (RAW) screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. The RAW determined that CPT code 33020 should be surveyed for April 2018; CPT code 33025 (*Creation of pericardial window or partial resection for drainage*) was included for review as part of this code family.

We disagree with the RUC-recommended work RVU of 14.31 (25th percentile survey value) for CPT code 33020 and are proposing a work RVU of 12.95. Our proposed work RVU is based on a crosswalk to CPT code 58700 (*Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)*), which has an identical work RVU of 12.95, identical 60 minutes intraservice time, and near identical total time values as CPT code 33020.

In our review of CPT code 33020, we note that the RUC-recommended intraservice time is decreasing from 85 minutes to 60 minutes (29 percent reduction), and that the RUC-recommended total time is decreasing from 565 minutes to 321 minutes (43 percent reduction). However, the RUC-recommended work RVU is only decreasing from 14.95 to 14.31, which is a reduction of less than 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 33020, we believe that it would be more accurate to propose a work RVU of 12.95, based on a crosswalk to CPT code 58700 to account for these decreases in surveyed work times.

For CPT code 33025, the RUC recommended a work RVU of 13.20 (survey 25th percentile value). Although we disagree with the RUC-recommended work RVU of 13.20, based on RUC survey results and the time resources involved in furnishing these two procedures we agree that the relative difference in work RVUs between CPT codes 33020 and 33025 is equivalent to the RUC-recommended incremental difference of 1.11 less work RVUs. Therefore, we are proposing a work RVU of 11.84 based on a reference to CPT code 34712 (*Transcatheter delivery of enhanced fixation devices(s) to the endograft (e.g., anchor, screw,*

tack) and all associated radiological supervision and interpretation), which has a work RVU of 12.00, identical intraservice time of 60 minutes, and similar total time as CPT code 33025.

In reviewing CPT code 33025, we note that the RUC-recommended intraservice time is decreasing from 66 minutes to 60 minutes (9 percent reduction), and that the RUC-recommended total time is decreasing from 410 minutes to 301 minutes (27 percent reduction). However, the RUC-recommended work RVU is only decreasing from 13.70 to 13.20, which is a reduction of less than 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 33025, we believe that it would be more accurate to propose a work RVU of 11.84, based on less the incremental difference of 1.11 work RVUs between CPT codes 33020 and 33025 and a crosswalk to CPT code 34712 to account for these decreases in surveyed work times.

We are proposing the RUC-recommended direct PE inputs for all the codes in this family.

(11) Transcatheter Aortic Valve Replacement (TAVR) (CPT Codes 33361, 33362, 33363, 33364, 33365, and 33366)

In October 2016, the RUC's RAW reviewed codes that had been flagged in the period from October 2011 to April 2012, using 3 years of available Medicare claims data (2013, 2014 and preliminary 2015 data). The RUC workgroup determined that the technology for these transcatheter aortic valve replacement (TAVR) services was evolving, as the typical site of service had shifted from being provided in academic centers to private centers, and the RUC recommended that CPT codes 33361–33366 be resurveyed for physician work and practice expense. These six codes were surveyed and reviewed at the April 2018 RUC meeting using a survey methodology that reflected the unique nature of these codes. CPT codes 33361–33366 are currently the only codes on the PFS where the -62 co-surgeon modifier is required 100 percent of the time.

We are proposing the RUC-recommended work RVU for all six of the codes in this family. We are proposing a work RVU of 22.47 for CPT code 33361 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach*), a work RVU of 24.54 for CPT code 33362 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach*), a work RVU of 25.47 for CPT code 33363 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach*), a work RVU of 25.97 for CPT code 33364 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach*), a work RVU of 26.59 for CPT code 33365 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)*), and a work RVU of 29.35 for CPT code 33366 (*Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)*).

Although we have some concerns that the RUC-recommended work RVUs for these six codes do not match the decreases in surveyed work time, we recognize that the technology described by the TAVR procedures is in the process of being adopted by a much wider audience, and that there will be greater intensity on the part of the practitioner when this particular new technology is first being adopted. However, we intend to continue examining whether these services are appropriately valued, in light of the proposed national coverage determination proposing to use TAVR for the treatment of symptomatic aortic valve stenosis that we posted on March 26, 2019. We will also consider any further improvements to the valuation of these services, as their use becomes more commonplace, through future notice and comment rulemaking. The text of the proposed national coverage determination is available on the CMS website at *https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=293*.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(12) Aortic Graft Procedures (CPT Codes 338XX, 338X1, 33863, 33864, 338X2, and 33866)

In 2017, CPT created a new add-on code, CPT code 33866 (*Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)*). For CY 2019, we finalized the RUC's recommended work RVU for this code on an interim basis (83 FR 59528). CPT revised the code set to develop distinct codes for ascending aortic repair for dissection and ascending aortic repair for other ascending aortic disease such as aneurysms and congenital anomalies, creating two new codes, as well as revaluating the two other codes in the family.

For CPT code 338XX (*Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection*), we disagree with the RUC-recommended work RVU of 65.00, because the RUC is recommending an increase in work RVU that is not commensurate with a reduction in physician time, and because we do not believe that the RUC's recommendation that this service be increased to a value that would place it among the highest valued of all services of similar physician time is appropriate; we think a comparison to other services of similar time indicates that the RUC's recommended increase overstates the work. Instead, we are proposing to increase the work RVU to 63.40 based on a crosswalk to CPT code 61697 (*Surgery of complex intracranial aneurysm, intracranial approach; carotid circulation*). For CPT code 338X1 (*Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (e.g., aneurysm)*), we disagree with the RUC-recommended work RVU of 50.00, because we do not believe it adequately reflects the recommended decrease in physician time, and because we do not believe this service should be assigned a value that is among the highest of all 90-day global services with similar physician time values. Instead, we are proposing a work RVU of 45.13 based on a crosswalk to CPT code 33468 (*Tricuspid valve repositioning and plication for Ebstein anomaly*), which is a code with an identical intraservice time and similar total time value.

For CPT code 33863 (*Ascending aorta graft, with cardiopulmonary bypass, with aortic root replacement using valved conduit and coronary reconstruction (e.g., Bentall)*), according to the RUC, the survey respondents underestimated the intraservice time of the procedure and the RUC recommended a work RVU of 59.00 based on the 75th percentile of survey responses for intraservice time. We believe the use of the survey 75th percentile value to be problematic, as the intraservice time values should generally reflect the survey median. We are requesting that this code be

resurveyed to determine more accurate physician time values, and we are proposing to maintain the current RVU of 58.79 for CY 2020. For CPT code 33864 (*Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (e.g., David Procedure, Yacoub procedure)*), we do not agree with the RUC-recommended work RVU of 63.00, because we believe this increase is not justified given that the intraservice time is not changing from its current value, and the physician total time value is decreasing. Therefore, we are proposing to maintain the current work RVU of 60.08 for this service.

For CPT code 338X2 (*Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (e.g., island pedicle or individual arch vessel reimplantation)*), we disagree with the RUC's recommended work RVU of 65.75. While we agree that an increase in work RVU is justified, as discussed above, we believe that the use of the 75th percentile of physician intraservice work time is problematic, and believe such a significant increase in work RVU is not validated. Therefore, we are proposing a less significant increase to 60.88 using the RUC-recommended difference in work value between CPT code 338X1 and the code in question, CPT code 338X2 (a difference of 15.75). As further support for this value, we note that it falls between CPT codes 33782 (*Aortic root translocation with ventricular septal defect and pulmonary stenosis repair (i.e., Nikaidoh procedure); without coronary ostium reimplantation*), which has a work RVU of 60.08, and CPT code 43112 (*Total or near total esophagectomy, with thoracotomy; with pharyngogastrostomy or cervical esophagogastrostomy, with or without pyloroplasty (i.e., McKeown esophagectomy or tri-incisional esophagectomy)*), which has a work RVU of 62.00. Both of these bracketing reference codes have similar intraservice and total time values. For CPT code 33X01 (*Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)*), we are proposing the RUC-recommended work RVU of 17.75.

For the direct PE inputs, we are proposing to refine the clinical labor to align with the number of post-operative visits. Thus, we are proposing to add 12 minutes of clinical labor time for ''Discharge day management'' for CPT codes 338X1, 33863, 33864, and 338X2, as each of these codes include a 99238 discharge visit within their global periods that should be reflected in the clinical labor inputs.

(13) Iliac Branched Endograft Placement (CPT Codes 34X00 and 34X01)

For CY 2018, the CPT Editorial Panel created a family of 20 new and revised codes that redefined coding for endovascular repair of the aorta and iliac arteries. The iliac branched endograft technology has become more mainstream over time, and two new CPT codes were created to capture the work of iliac artery endovascular repair with an iliac branched endograft. These two new codes were surveyed and reviewed for the January 2019 RUC meeting.

We are proposing the RUC-recommended work RVU of 9.00 for CPT code 34X00 (*Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral*) and the RUC-recommended work RVU of 24.00 for CPT code 34X01 (*Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(14) Exploration of Artery (CPT Codes 35701, 35X01, and 35X01)

CPT code 35701 (*Exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*) was identified via a screen for services with a ne.g.ative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes. In September 2018, the CPT Editorial Panel revised one code, added two new codes, and deleted three existing codes in the family to report major artery exploration procedures and to condense the code set due to low frequency.

We are proposing the RUC-recommended work RVU for all three codes in the family. We are proposing a work RVU of 7.50 for CPT code 35701, a work RVU of 7.12 for CPT code 35X00 (*Exploration not followed by surgical repair, artery; upper extremity (e.g., axillary, brachial, radial, ulnar)*), and a work RVU of 7.50 for CPT code 35X01 (*Exploration not followed by surgical repair, artery; lower extremity (e.g., common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)*).

For the direct PE inputs, we are proposing to refine the clinical labor, supplies, and equipment to match the number of office visits contained in the global periods of the codes under review. We are proposing to refine the clinical labor time for the ''Post-operative visits (total time)'' (CA039) activity from 36 minutes to 27 minutes for CPT codes 35701 and 35X00, and from 63 minutes to 27 minutes for CPT code 35X01. Each of these CPT codes contains a single postoperative level 2 office visit (CPT code 99212) in its global period, and 27 minutes of clinical labor is the time associated with this office visit. We are proposing to refine the equipment time for the exam table (EF023) to the same time of 27 minutes for each code to match the clinical labor time. Finally, we are also proposing to refine the quantity of the minimum multi-specialty visit pack (SA048) from 2 to 1 for CPT code 35X01 to match the single postoperative visit in the code's global period. We believe that the additional direct PE inputs in the recommended materials were an accidental oversight due to revisions that took place at the RUC meeting following the approval of the PE inputs for these codes.

(15) Intravascular Ultrasound (CPT Codes 37252 and 37253)

In CY 2014, the CPT Editorial Panel deleted CPT codes 37250 (*Ultrasound evaluation of blood vessel during*

diagnosis or treatment)and 37251 (*Ultrasound evaluation of blood vessel during diagnosis or treatment*) and created new bundled codes 37252 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel*) and 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel*) to describe intravascular ultrasound (IVUS). CPT codes 37252 and 37253 were reviewed at the January 2015 RUC meeting. The RUC's recommendation for these codes were to result in an overall work savings that should have been redistributed back to the Medicare conversion factor. The codes have had a 44 percent increase in work RVUs over the old codes, CPT codes 37250 and 37251, from 2015 to 2016 and the utilization has doubled from that of the previous coding structure, not considering the radiological activities. In April 2018, the RUC reviewed this code family and determined the utilization of the bundling of these services was underestimated. Consequently, the RUC recommended that these services be surveyed for October 2018. The RUC indicated that the specialty societies should research why there was such an increase in the utilization. Accordingly, the specialty society surveyed these ZZZ-day global codes, and the survey results indicated the intraservice and total work times, along with the work RVU should remain the same despite the underestimation in utilization.

We disagreed with the RUC-recommended work RVU of 1.80 for CPT code 37252 and are proposing a work RVU of 1.55 based on a crosswalk to CPT code 19084. CPT code 19084 is a recently reviewed code with 20 minutes of intraservice time and 25 minutes of total time. In reviewing CPT code 37252, we note, as mentioned above, that in CY 2015 the specialty society stated that bundling this service would achieve savings. However, since 2015 observed utilization for CPT code 37252 has greatly exceeded proposed estimates, thus we are proposing to restore work neutrality to the intravascular ultrasound code family to achieve the initial estimated savings.

For CPT code 37253, we disagreed with the RUC-recommended work RVU of 1.44 and we are proposing a work RVU of 1.19. Although we disagreed with the RUC-recommended work RVU, we note the relative difference in work between CPT codes 37252 and 37253 is an interval of 0.36 RVUs. Therefore, we are proposing a work RVU of 1.19 for CPT code 37253, based on the recommended interval of 0.36 fewer RVUs than our proposed work RVU of 1.55 for CPT code 37252.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(16) Stab Phlebectomy of Varicose Veins (CPT Codes 37765 and 37766)

These services were identified in February 2008 via the High Volume Growth screen, for services with a total Medicare utilization of 1,000 or more that have increased by at least 100 percent from 2004 through 2006. The RUC subsequently recommended monitoring and reviewing changes in utilization over multiple years. In October 2017, the RUC recommended that this service be surveyed for April 2018. We are proposing the RUC-recommended work RVUs of 4.80 for CPT code 37765 (*Stab phlebectomy of varicose veins, 1 extremity; 10–20 stab incisions*) and 6.00 for CPT code 37766 (*Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions*). We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(17) Biopsy of Mouth Lesion (CPT Code 40808)

CPT code 40808 (*Biopsy, vestibule of mouth*) was identified via a screen for services with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS/Other source codes.

We disagree with the RUC's recommended work RVU of 1.05 with a crosswalk to CPT code 11440 (*Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less*), as we believe this increase in work RVU is not commensurate with the RUC-recommended 5-minute reduction in intraservice time and a 10-minute reduction in total time. While we understand that the RUC considers the current time values for this service to be invalid estimations, we do not see compelling evidence that would indicate that an increase in work RVU that would be concurrent with a reduction in physician time is appropriate. Therefore, we are proposing to maintain the current work RVU of 1.01, and note that implementing the current work RVU with the RUC-recommended revised physician time values would correct the negative IWPUT anomaly.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity to 3 minutes and to refine the clinical labor time for the ''Confirm order, protocol exam'' (CA014) activity to 0 minutes. As we detailed when discussing this issue in the CY 2019 PFS final rule (83 FR 59463 through 59464), CPT code 40808 does not include the old clinical labor task ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' on a prior version of the PE worksheet, nor does the code contain any clinical labor for the CA007 activity (''Review patient clinical extant information and questionnaire''). CPT code 40808 does not appear to be an instance where an old clinical labor task was split into two new clinical labor activities, and we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code. We also note that there is no effect on the total clinical labor direct costs in these situations, since the same 3 minutes of clinical labor time is still being furnished.

We are also proposing to refine the equipment time for the electrocautery-hyfrecator (EQ110) to conform to our established standard for non-highly technical equipment.

(18) Transanal Hemorrhoidal Dearterialization (CPT Codes 46945, 46946, and 46X48)

We are proposing the RUC-recommended work RVU for all three codes in the family. We are proposing a work RVU of 3.69 for CPT code 46945 (*Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance*), a work RVU of 4.50 for CPT code 46946 (*2 or more hemorrhoid columns/groups, without imaging guidance*), and a work RVU of 5.57 for CPT code 46X48 (*Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy when performed*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(19) Preperitoneal Pelvic Packing (CPT Codes 490X1 and 490X2)

In May 2018, the CPT Editorial Panel approved the addition of two codes for preperitoneal pelvic packing, removal

and/or repacking for hemorrhage associated with pelvic trauma. These new codes were surveyed and reviewed for the October 2018 RUC meeting.

We disagree with the RUC-recommended work RVU of 8.35 for CPT code 490X1 (*Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration*) and are proposing a work RVU of 7.55 based on a crosswalk to CPT code 52345 (*Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (e.g., balloon dilation, laser, electrocautery, and incision)*). We are also proposing to reduce the immediate postservice work time from 60 minutes to 45 minutes, which results in a total work time of 140 minutes for this procedure. We believe that the survey respondents overstated the immediate postservice work time that would typically be required to perform CPT code 490X1, which we investigated by comparing this new service against the existing 0-day global codes on the PFS. We found that among the roughly 1,100 codes with 0-day global periods, only 21 codes had an immediate postservice work time of 60 minutes or longer. The 21 codes that fell into this category had significantly higher intraservice work times than CPT code 490X1, with an average intraservice work time of 111 minutes as compared to the 45 minutes of intraservice work time in CPT code 490X1. Generally speaking, it is extremely rare for a service to have more immediate postservice work time than intraservice work time, and in fact only 28 out of the roughly 1,100 codes with 0-day global periods had more immediate postservice work time than intraservice work time. While we agree that each service on the PFS is its own unique entity, these comparisons to other 0-day global codes suggest that the survey respondents overestimated the amount of immediate postservice work time that would typically be associated with CPT code 490X1.

As a result, we believe that it would be more accurate to reduce the immediate postservice work time to 45 minutes and to propose a work RVU of 7.55 based on a crosswalk to CPT code 52345. This crosswalk code shares an intraservice work time of 45 minutes and a similar total time of 135 minutes after taking into account the reduced immediate postservice work time that we are proposing for CPT code 490X1. We searched the RUC database for 0-day global procedures with 45 minutes of intraservice work time, and at the recommended work RVU of 8.35, CPT code 490X1 would establish a new maximum value, higher than all of the 79 other codes that fall into this category. We recognize that CPT code 490X1 describes a preperitoneal pelvic packing service associated with pelvic trauma, and that this is a difficult and intensive procedure that rightly has a higher work RVU than many of these other 0-day global codes. However, we believe that it better maintains relativity to propose a crosswalk to CPT code 52345 at a work RVU of 7.55, which would still assign this code the second-highest work RVU among all 0 day global codes with 45 minutes of intraservice work time, as opposed to proposing the survey median work RVU of 8.35 at a rate higher than anything in the current RUC database.

We disagree with the RUC-recommended work RVU of 6.73 for CPT code 490X2 (Re-exploration of pelvic wound with removal of preperitoneal pelvic packing including repacking, when performed) and are proposing a work RVU of 5.70 based on the 25th percentile survey value. We believe that the survey 25th percentile work RVU more accurately describes the work of re-exploring this type of pelvic wound, and by proposing the survey 25th percentile we are maintaining the general increment in RVUs between the two codes in the family (a difference of 1.62 RVUs as recommended by the RUC as compared to 1.85 RVUs as proposed here). We are supporting this valuation with a reference to CPT code 39401 (*Mediastinoscopy; includes biopsy(ies) of mediastinal mass (e.g., lymphoma), when performed*), a recently reviewed code from CY 2015 which shares the same intraservice time of 45 minutes, a slightly higher total time of 142 minutes and a lower work RVU of 5.44.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(20) Cystourethroscopy Insertion Transprostatic Implant (CPT Codes 52441 and 52442)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the AMA/Specialty Society RVS Update Committee. This service was reviewed at the October 2018 RAW meeting, and the RAW indicated that the utilization is increasing and questioned the time required to perform these services. These two codes were surveyed and reviewed for the January 2019 RUC meeting.

We disagree with the RUC-recommended work RVU of 4.50 (current value) for CPT code 52441 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant*) and are proposing a work RVU of 4.00. This proposed work RVU is based on a crosswalk from recently reviewed CPT code 58562 (*Hysterscopy, surgical; with removal of impacted foreign body*), which has a work RVU of 4.00, and an identical 25 minutes of intraservice time as CPT code 52441.

We disagree with the RUC-recommended work RVU of 1.20 (current value) for CPT code 52442 (*Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)*) and are proposing a work RVU of 1.01. This proposed work RVU is based on a crosswalk from CPT code 36218 (*Selective catheter placement, arterial system; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family (List in addition to code for initial second or third order vessel as appropriate)*), which has a work RVU of 1.01, and an identical 15 minutes of intraservice time as CPT code 52442. The RUC survey showed a reduction in time, and the work should reflect these changes.

We are proposing the RUC-recommended direct PE inputs for all codes in the family without refinement.

(21) Orchiopexy (CPT Code 54640)

The CPT Editorial Panel revised existing CPT code 54640 to describe an additional approach for orchiopexy (scrotal) and to clearly indicate that hernia repair is separately reportable. This code was surveyed and reviewed for the January 2019 RUC meeting.

We are proposing to maintain the current work RVU of 7.73 as recommended by the RUC. We are proposing the RUC-recommended direct PE inputs for CPT code 54640 without refinement.

(22) Radiofrequency Neurootomy Sacroiliac Joint (CPT Codes 6XX00, 6XX01)

In September 2018, the CPT Editorial Panel created two new codes to describe injection and radiofrequency ablation of the sacroiliac joint with image guidance for somatic nerve procedures. We are proposing the RUC-recommended work RVU of 1.52 for CPT code 6XX00 (*Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)*) and the RUC-recommended work RVU of 3.39 for CPT code 6XX01 (*Radiofrequency ablation, nerves innervating the sacroiliac joint, with*

image guidance (i.e., fluoroscopy or computed tomography)).

For the direct PE inputs, we are proposing to refine the quantity of the ''needle, 18–26g 1.5–3.5in, spinal'' (SC028) supply from 3 to 1 for CPT code 6XX00. There are no spinal needles in use in the reference code associated with CPT code 6XX00, and there was no explanation in the recommended materials explaining why three such needles would be typical for this procedure. We agree that the service being performed in CPT code 6XX00 would require a spinal needle, but we do not believe that the use of three such needles would be typical.

We are proposing to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 4 to 2 for CPT code 6XX01. We do not believe that the use of 4 of these cannula would be typical for the procedure, as the reference code currently used for destruction by neurolytic agent contains only a single cannula. We believe that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating four of them simultaneously as suggested in the recommended direct PE inputs. We also searched in the RUC database for other CPT codes that made use of the SD011 supply, and out of the seven codes that currently use this item, none of them include more than 2 cannula. As a result, we are proposing to refine the supply quantity to 2 cannula to match the highest amount contained in an existing code on the PFS. We are also refining the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 164 minutes to 82 minutes. The RUC's equipment time recommendation was predicated on the use of 4 of the SD011 supplies for 41 minutes apiece, and we are refining the equipment time to reflect our supply refinement to 2 cannula. It was unclear in the recommended materials as to whether the radiofrequency kit equipment was in use simultaneously or sequentially along with the cannula supplies, and therefore, we are soliciting comments on the typical use of this equipment.

Finally, we are proposing to refine the equipment time for the technologist PACS workstation (ED050) equipment to match our standard equipment time formulas, which results in an increase of 5 minutes of equipment time for both codes.

(23) Lumbar Puncture (CPT Codes 62270, 622X0, 62272, and 622X1)

In October 2017, these services were identified as being performed by a different specialty than the specialty that originally surveyed this service. In January 2018, the RUC recommended that these services be referred to CPT to bundle image guidance. At the September 2018 CPT Editorial Panel meeting, the Panel created two new codes to bundle diagnostic and therapeutic lumbar puncture with fluoroscopic or CT image guidance and revised the existing diagnostic and therapeutic lumbar puncture codes so they would only be reported without fluoroscopic or CT guidance.

For CPT code 62270 (*Spinal puncture, lumbar, diagnostic*), we disagree with the RUC-recommended work RVU of 1.44 and we are proposing a work RVU of 1.22 based on a crosswalk to CPT code 40490 (*Biopsy of lip*). CPT code 40490 has the same intraservice time of 15 minutes and 2 additional minutes of total time. In reviewing CPT code 62270, we noted that the recommended intraservice time is decreasing from 20 minutes to 15 minutes (25 percent reduction), and the recommended total time is decreasing from 40 minutes to 32 minutes (20 percent reduction); however, the RUC-recommended work RVU is increasing from 1.37 to 1.44, which is an increase of just over 5 percent. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 62270, we believed that it was more accurate to propose a work RVU of 1.22 based on a crosswalk to CPT code 40490 to account for these decreases in the surveyed work time.

For CPT code 622X0 (*Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance*), we disagree with the RUC-recommended work RVU of 1.95 and we are proposing a work RVU of 1.73. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 622X0 is equivalent to an interval of 0.51 RVUs. Therefore, we are proposing a work RVU of 1.73 for CPT code 622X0, based on the recommended interval of 0.51 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

For CPT code 62272 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter*), we disagree with the RUC-recommended work RVU of 1.80 and we are proposing a work RVU of 1.58. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 622X0 is equivalent to the RUC-recommended interval of 0.36 RVUs. Therefore, we are proposing a work RVU of 1.58 for CPT code 62272, based on the recommended interval of 0.36 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

For CPT code 622X1 (*Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance*), we disagree with the RUC-recommended work RVU of 2.25 and we are proposing a work RVU of 2.03. Although we disagree with the RUC-recommended work RVU, we note that the relative difference in work between CPT codes 62270 and 622X1 is equivalent to the recommended interval of 0.81 RVUs. Therefore, we are proposing a work RVU of 2.03 for CPT code 622X1, based on the recommended interval of 0.81 additional RVUs above our proposed work RVU of 1.22 for CPT code 62270.

(24) Electronic Analysis of Implanted Pump (CPT Codes 62367, 62368, 62369, and 62370)

CPT code 62368 (*Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming*) was identified by the RUC on a list of services which were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along with three other codes in the family for PE only at the April 2018 RUC meeting. The RUC did not recommend work RVUs for these codes and we are not proposing to change the current work RVUs.

For the direct PE inputs, we are proposing to remove the minimum multi-specialty visit pack (SA048) from CPT code 62370 as a duplicative supply due to the fact that this code is typically billed with an E/M or other evaluation service.

(25) Somatic Nerve Injection (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450)

In May 2018, the CPT Editorial Panel approved the revision of descriptors and guidelines for the codes in this family and the deletion of three CPT codes to clarify reporting (*i.e., separate reporting of imaging guidance, number of units and a change from a 0-day global to ZZZ for one of the CPT codes in this*

family). This family of services describe the injection of an anesthetic agent(s) and/or steroid into a nerve plexus, nerve, or branch; reported once per nerve plexus, nerve, or branch as described in the descriptor regardless of the number of injections performed along the nerve plexus, nerve, or branch described by the code.

CPT codes 64400 (*Injection(s), anesthetic agent(s); trigeminal nerve, each branch (ie ophthalmic, maxillary, mandibular)), 64408 (Injection(s), anesthetic agent(s), and/or steroid; vagus nerve*), 64415 (*Injection(s), anesthetic agent(s) and/or steroid; brachial plexus), 64416 (Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)*), 64417 (*Injection(s), anesthetic agent(s) and/or steroid; axillary nerve), 64420 (Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level*), 64421 (*Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure*)), 64425 (*Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves*), 64430 (*Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve), 64435 (Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve*), 64445 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve*), 64446 (*Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)*), 64447 (*Injection(s), anesthetic agent(s); femoral nerve*), 64448 (*Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)*), 64449 (*Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)*), and 64450 (*Injection(s), anesthetic agent(s); other peripheral nerve or branch*) were reviewed for work and PE at the October 2018 RUC meeting. The PE for CPT code 64450 was re-reviewed during the RUC January 2019 meeting.

During the October 2018 RUC presentation for this family of services, the specialty societies stated that CPT codes 64415, 64416, 64417, 64446, 66447, and 64448 were reported with CPT code 76942 (*Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation)* more than 50 percent of the time. Specifically, 76 percent with CPT code 64415, 85 percent with CPT code 64416, 68 percent with CPT code 64417, 77 percent with CPT code 64446, 77 percent with CPT code 66447, and 79 percent with CPT code 64448. It was also noted in the RUC recommendations that this overlap was accounted for in the RUC recommendations submitted for these services. Furthermore, the RUC recommendations sated that the RUC referred CPT codes 64415, 64416, 64417, 64446, 64447 and 64448 to be bundled with ultrasound guidance, CPT code 76942 to the CPT Editorial Panel for CPT 2021.

In reviewing this family of services, our proposed work and PE values for CPT codes 64415, 64416, 64417, 64446, 64447 and 64448 do not consider the overlap of imaging as noted in the RUC recommendations. We note that the RUC recommendations did not include values to support the valuation for the bundling of imaging in their work or PE recommendations and that the CPT code descriptors do not state that imaging is included.

For CY 2020, we are proposing the RUC-recommended work RVUs for CPT codes 64417 (work RVU of 1.27), 64435 (work RVU of 0.75), 64447 (work RVU of 1.10), and 64450 (work RVU of 0.75), the RUC reaffirmed work RVU of 0.94 for CPT code 64405 (*Injection, anesthetic agent; greater occipital nerve*), which is the current work RVU finalized in the CY 2019 final rule (83 FR 59542), and the RUC reaffirmed work RVU of 1.10 for CPT code 64418 (*Injection, anesthetic agent; suprascapular nerve*), which is the current work RVU value finalized in the CY 2018 final rule (82 FR 53054). Although we are proposing the RUC reaffirmed work RVUs for these two codes, as submitted in the RUC recommendations, we note that comparable codes in this family of services have lower work RVUs. Thus, these two codes may have become misvalued since their last valuation, as they were not resurveyed under this code family during the October 2018 RUC meeting.

In continuing our review of this code family, we disagree with the RUC-recommended work RVU of 1.00 for CPT code 64400 and are proposing a work RVU of 0.75, to maintain rank order in this code family. Our proposed work RVU is based on a crosswalk to another code in this family, CPT code 64450, which has an identical work RVU of 0.75 and near identical intraservice and total time values to CPT code 64400.

We note that the RUC-recommended intraservice time decreased from 37 to 6 minutes (84 percent reduction) and the RUC-recommended total time decreased from 69 to 20 minutes (71 percent reduction) for CPT code 64400. However, the RUC-recommended work RVU only decreased by 0.11, a 10 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64400, we believe that it would be more accurate to propose a work RVU of .075 based on a crosswalk to CPT code 64450, which has an identical work RVU of 0.75 and near identical intraservice and total times to CPT code 64400. We further note that our proposed work RVU maintains rank order in this code family among comparable codes.

For CPT code 64408, we disagree with the RUC-recommended work RVU of 0.90 and are proposing a work RVU of 0.75, to maintain rank order in this code family. Our proposed work RVU is based on a crosswalk to another code in this family, CPT code 64450, which has an identical work RVU of 0.75, and near identical intraservice and total time values to CPT code 64408.

We note that the RUC-recommended intraservice time decreased from 16 to 5 minutes (69 percent reduction) and RUC-recommended total time decreased from 36 to 20 minutes (44 percent reduction) for CPT code 64408. Although the RUC-recommended work RVU decreased by 0.51, a 36 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64408, we believe that it would be more accurate to propose a work RVU of .075, based on a crosswalk CPT code 64450,

to account for these decrease in the surveyed work times. We further note that our proposed work RVU maintains rank order in this code family among comparable codes.

For CPT code 64415, we disagree with the RUC-recommended work RVU of 1.42 and are proposing a work RVU of 1.35, based on our time ratio methodology and further supported by a reference to CPT code 49450 (*Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injections(s), image documentation and report*), which has a work RVU of 1.36 and similar intraservice and total time values to CPT code 64415.

We note that the RUC-recommended intraservice time decreased from 15 to 12 minutes (20 percent reduction) and RUC-recommended total time decreased from 44 to 40 minutes (9 percent reduction). However, the RUC-recommended work RVU only decreased by 0.06, which is a 4 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64415, we believe that it would be more accurate to propose a work RVU of 1.35, based on our time ratio methodology and a reference to CPT code 49450, to account for these decrease in the surveyed work times.

For CPT code 64416, we disagree with the RUC-recommended work RVU of 1.81 and are proposing a work RVU of 1.48, based on our time ratio methodology and further supported by a bracket of CPT code 62270 (*Spinal puncture, lumbar, diagnostic*), which has a work RVU of 1.37, identical intraservice, and similar total time to CPT code 64416 and CPT code 91035 (*Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation*), which has a work RVU of 1.59, identical intraservice, and near identical total time values to CPT code 64416.

We note that while the RUC-recommended intraservice time remained unchanged, the RUC-recommended total time decreased from 60 to 49 minutes (18 percent reduction). However, the RUC recommended maintaining the current work RVU of 1.81. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed total time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64416, we believe that it would be more accurate to propose a work RVU of 1.48, based on our time ratios methodology and a bracket of CPT code 62270 and CPT code 91035, to account for these decreases in the surveyed work times.

For CPT code 64420, we disagree with the RUC-recommended work RVU of 1.18 and are proposing a work RVU of 1.08, based on our time ratio methodology and further supported by a reference to CPT code 12011 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less*), which has a work RVU of 1.07 and similar intraservice and total time values to CPT code 64420.

We note that the RUC-recommended intraservice time decreased from 17 to 10 minutes (41 percent reduction) and the RUC-recommended total time decreased from 37 to 34 minutes (8 percent reduction). However, the RUC recommended to maintaining the current work RVU of 1.18. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64420, we believe that it would be more accurate to propose a work RVU of 1.08 based on our times ratio methodology and a crosswalk to CPT code 12011, to account for these decreases in the surveyed work times.

For CPT code 64421, we disagree with the RUC-recommended work RVU of 0.60 and are proposing a work RVU of 0.50, based on our time ratio methodology and to maintain rank order among comparable codes in the family. Our proposed work RVU is further supported by a crosswalk to CPT code 15276 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), which has a work RVU of 0.50 and identical intraservice and total times to CPT code 64421.

We note that our time ratio methodology suggests the code is better valued at 0.50. Furthermore, the RUC-recommended work RVU of 0.60 creates a rank order anomaly in the code family. In the case of CPT code 64421, we believe that it would be more accurate to propose a work RVU of 0.50, based on our time ratio methodology and a crosswalk to CPT code 15276, to maintain rank order among comparable codes in the family.

For CPT code 64425, we disagree with the RUC-recommended work RVU of 1.19 and are proposing a work RVU of 1.00, to maintain rank order among comparable codes in the family, based on a bracket of CPT code 12001 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less*) which has a work RVU of 0.84 and near identical intraservice and total time values to CPT code 64425 and CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*), which has a work RVU of 1.10 and near identical intraservice and total times to CPT code 64425.

We note that the RUC-recommended work RVU of 1.19 creates a rank order anomaly in the code family. In the case of CPT code 64425, we believe that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 12001 and 30901 to maintain rank order among comparable codes in the family.

For CPT code 64430, we disagree with the RUC-recommended work RVU of 1.15 and are proposing a work RVU of 1.00, to maintain rank order among comparable codes in the family, based on a bracket of CPT code 45330 (*Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*), which has a work RVU of 0.84 and near identical

intraservice and total time values to CPT code 64430 and CPT code 31576 (*Laryngoscopy, flexible; with biopsy(ies)*), which has a work RVU of 1.89 and near identical intraservice and total time values to CPT code 64430.

We note that the RUC-recommended intraservice time decreased from 17 to 10 minutes (41 percent reduction) and the RUC-recommended total time increased from 39 to 43 minutes (10 percent increase). While the RUC-recommended work RVU is decreasing by 0.31, a 21 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64430, we believe that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 45300 and 31576 to account for these decreases in surveyed work times and to maintain rank order among comparable codes in this family.

For CPT code 64445, we disagree with the RUC-recommended work RVU of 1.18 and are proposing a work RVU of 1.00, based on our time ratio methodology and to maintain rank order among comparable codes in the family. Our proposed work RVU is based on a bracket of CPT code 12001 (*Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less*), which has a work RVU of 0.84 and near identical intraservice and total times to CPT code 64445 and CPT code 30901 (*Control nasal hemorrhage, anterior, simple (limited cautery and/or packing) any method*), which has a work RVU of 1.10 and near identical intraservice and total time values to CPT code 64445.

We note that the RUC-recommended intraservice time decreased from 15 to 10 minutes (33 percent reduction) and the RUC-recommended total time decreased from 48 to 24 minutes (50 percent reduction). While the RUC-recommended work RVU is decreasing by 0.30, a 21 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64445, we believe that it would be more accurate to propose a work RVU of 1.00, based on a bracket of CPT codes 12001 and 30901 to account for these decreases in surveyed work times and to maintain rank order among comparable codes in the family.

For CPT code 64446, we disagree with the RUC-recommended work RVU of 1.54 and are proposing a work RVU of 1.36 based on our time ratios methodology and further supported by a reference to CPT code 51710 (*Change of cystostomy tube; complicated*), which has a near identical work RVU of 1.35 and near identical intraservice and total time values to CPT code 64446.

We note that RUC-recommended intraservice time decreased from 20 to 15 minutes (25 percent reduction) and the RUC-recommended total time decreased from 64 to 40 minutes (38 percent reduction). While the RUC-recommended work RVU is decreasing by 0.27, a 15 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64446, we believe that it would be more accurate to propose a work RVU of 1.36, based on our time ratios methodology and a reference to CPT code 51710 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For CPT code 64448, we disagree with the RUC-recommended work RVU of 1.55 and are proposing a work RVU of 1.41, based our time ratio methodology and a reference to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*), which has a work RVU of 1.48 and near identical intraservice time and identical total time values to CPT code 64448.

We note that RUC-recommended intraservice time decreased from 15 to 13 minutes (13 percent reduction) and the RUC-recommended total time decreased from 55 to 38 minutes (62 percent reduction). While the RUC-recommended work RVU is only decreasing by 0.08, which is only a 5 percent reduction. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. In the case of CPT code 64448, we believe that it would be more accurate to propose a work RVU of 1.41, based on our time ratios methodology and a crosswalk to CPT code 27096 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For CPT code 64449, we disagree with the RUC-recommended work RVU of 1.55 and are proposing a work RVU of 1.27, based our time ratio methodology and a reference to CPT code 11755 (*Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)*), which has a work RVU of 1.25 and near identical intraservice and total times to CPT code 64449.

We note that RUC-recommended intraservice time decreased from 20 to 14 minutes (30 percent reduction) and the RUC-recommended total time decreased from 60 to 38 minutes (37 percent reduction). While the RUC-recommended work RVU is decreasing by 0.26, a 14 percent reduction, we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed intraservice work time for the procedure. Although we do not imply that the decrease in time as reflected in survey values must always equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work and time are intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to

work RVUs. In the case of CPT code 64449, we believe that it would be more accurate to propose a work RVU of 1.27, based on our time ratios methodology and a reference to CPT code 11755 to account for these decreases in surveyed times and to maintain rank order among comparable codes in the family.

For the direct PE inputs, we are proposing to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 64450. This code does not currently include this clinical labor time, and unlike the new code, CPT code 64XX1, in the Genicular Injection and RFA code family, in which the PE for CPT code 64450 was resurveyed at the January 2019 RUC for PE, CPT code 64450 does not include imaging guidance in its code descriptor. When CPT code 64450 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, it would be duplicative to include this clinical labor time in CPT code 64450. We are also proposing to refine the clinical labor time for the ''*Assist physician or other qualified healthcare professional—directly related to physician work time (100 percent)*'' (CA018) activity from 10 to 5 minutes for CPT code 64450, to match the intraservice work time and proposing to refine the equipment times in accordance with our standard equipment time formulas for CPT code 64450.

Additionally, we are proposing to refine the clinical labor time for the ''provide education/obtain consent'' (CA011) from 3 minutes to 2 minutes, for CPT codes 64400, 64408, 64415, 64417, 64420, 64425, 64430, 64435, 64445, 64447 and 64450, to conform to the standard for this clinical labor task. We are also proposing to refine the equipment time in accordance with our standard equipment time formula for these codes. We note that there were no RUC-recommended direct PE inputs provided for CPT codes 64416, 64446, and 64448.

(26) Genicular Injection and RFA (CPT Codes 64640, 64XX0, and 64XX1)

In May 2018, the CPT Editorial Panel approved the addition of two codes to report injection of anesthetic and destruction of genicular nerves by neurolytic agent. In October 2018, the RUC discussed the issues surrounding the survey of this family of services and supported the specialty societies' request for CPT codes 64640 (*Destruction by neurolytic agent; other peripheral nerve or branch*), 64XX0 (*Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed*), and 64XX1 (*Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed*) to be resurveyed and presented at the January 2019 RUC meeting, based on their concern that many survey respondents appeared to be confused about the number of nerve branch injections involved with these three codes. The RUC resurveyed these services at the January 2019 RUC meeting.

For CY 2020, we are proposing the RUC-recommended work RVUs for two of the three codes in this family. We are proposing the RUC-recommended work RVU of 1.98 (25th percentile survey value) for CPT code 64640 and the RUC-recommended work RVU of 1.52 (25th percentile survey value) for CPT code of 64XX0.

For CPT code 64XX1, we disagree with the RUC-recommended work RVU of 2.62, which is higher than the 25th percentile survey value, a work RVU 2.50, and are proposing a work RVU of 2.50 (25th percentile survey value) based on a reference to CPT code 11622 (*Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 1.1 to 2.0 cm*), which has a work RVU of 2.41 and near identical intraservice and total times to CPT code 64XX1.

In our review of CPT code 64XX1, we examined the intraservice time ratio for the new code, CPT code 64XX1, in relation to an existing code in this family of services, CPT code 64640. CPT code 64XX1 has a RUC-recommended work RVU of 2.62, 25 minutes of intraservice time, and 74 minutes of total time. CPT code 64640 has a RUC-recommended work RVU of 1.98, 20 minutes of intraservice time, and 64 minutes of total time. To derive our proposed work RVU of 2.50, we calculated the intraservice time ratio between these two codes, which is a calculated value of 1.25, and applied this ratio times the RUC-recommended work RVU of 1.98 for CPT code 64650, which resulted in a calculated value of 2.48. This value is nearly identical to the January 2018 RUC 25th percentile survey value for CPT code 64XX1, a work RVU of 2.50. Our proposed work RVU of 2.50 is further supported by a reference to CPT code 11622.

For the direct PE inputs, we are proposing to remove the clinical labor time for the ''Confirm availability of prior images/studies'' (CA006) activity for CPT code 64640. This code does not currently include this clinical labor time, and unlike the new code in the family (CPT code 64XX1), CPT code 64640 does not include imaging guidance in its code descriptor. When CPT code 64640 is performed with imaging guidance, it would be billed together with a separate imaging code that already includes clinical labor time for confirming the availability of prior images. As a result, it would be duplicative to include this clinical labor time in CPT code 64640. We are proposing to refine the clinical labor time for the ''Assist physician or other qualified healthcare professional—directly related to physician work time (100 percent)'' (CA018) activity from 25 to 20 minutes for CPT code 64640, to match the intraservice work time. We are also proposing to refine the equipment times in accordance with our standard equipment time formulas for CPT code 64640.

We are proposing the RUC-recommended direct PE inputs for CPT code 64XX0 without refinement.

For CPT code 64XX1, we are proposing to refine the quantity of the ''cannula (radiofrequency denervation) (SMK–C10)'' (SD011) supply from 3 to 1. We do not believe that the use of 3 of this supply item would be typical for the procedure. We note that the RUC recommendations for another code in this family, CPT code 64640 only contains 1 of this supply item. We believe that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating three of them simultaneously as suggested in the recommended direct PE inputs. We also searched in the RUC database for other CPT codes that made use of the SD011 supply, and out of the seven codes that currently use this item, none of them include more than 2 cannula. As a result, we are proposing to refine the supply quantity to 2 cannula to match the highest amount contained in an existing code on the PFS. We are also refining the equipment time for the ''radiofrequency kit for destruction by neurolytic agent'' (EQ354) equipment from 141 minutes to 47 minutes. The equipment time recommendation was predicated on the use of 3 of the SD011 supplies for 47 minutes apiece, and we are refining the equipment time to reflect our supply refinement to 1 cannula. It was unclear in the RUC recommendation materials as to whether the radiofrequency kit equipment was in use simultaneously or sequentially along with the cannula supplies, and therefore, we are soliciting comments on the typical use of this equipment.

(27) Cyclophotocoagulation (CPT Codes 66711, 66982, 66983, 66984, 66X01, and 66X02)

In October 2017, CPT codes 66711 (*Ciliary body destruction; cyclophotocoagulation, endoscopic*) and 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification*) were identified as codes reported together 75 percent of the time or more. The RUC reviewed action plans to determine whether a code bundle solution should be developed for these services. In January 2018, the RUC recommended to refer to CPT to bundle 66711 with 66984 for CPT 2020. In May 2018, the CPT Editorial Panel revised three codes and created two new codes, CPT codes 66X01 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation*) and 66X02 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation*) to differentiate cataract procedures performed with and without endoscopic cyclophotocoagulation.

The codes discussed above and CPT codes 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage*) and 66983 *(Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)*) were reviewed at the January 2019 RUC meeting.

For CY 2020, we are proposing the RUC-recommended work RVU of 10.25 for CPT code 66982, the RUC recommendation to contractor-price CPT code 66983, and the RUC-recommended work RVU of 7.35 for CPT code 66984. We disagree with the RUC recommendations for CPT codes 66711, 66X01, and 66X02.

For CPT code 66711, we disagree with the RUC-recommended work RVU of 6.36 and are proposing a work RVU of 5.62, based on crosswalk to CPT code 28285 (*Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy*), which has an identical work RVU of 5.62, and similar intraservice and total times.

In our review of CPT code 66711, we note that the recommended intraservice time is decreasing from 20 minutes to 10 minutes (33 percent reduction), and that the recommended total time is decreasing from 192 minutes to 191 minutes (0.5 percent reduction). While the RUC-recommended work RVU is decreasing from 7.93 to 6.36, which is a 20 percent reduction, we do not believe it appropriately accounts for the decreases in survey time. Time ratio methodology suggest that CPT code 66711 is better valued at a work RVU of 5.29, thus it is overvalued with consideration to the decreases in survey times. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 66711, we believe that it would be more accurate to propose a work RVU of 5.62, based on our time ratio methodology and a crosswalk to CPT code 28285 to account for these decreases in surveyed work times.

For CPT code 66X01, the RUC recommended a work RVU of 13.15, we disagree with the RUC-recommended work RVU and are proposing contractor-pricing for this code. In reviewing this code, we note that the RUC recommendation survey values do not support the RUC-recommended work RVU of 13.15 and furthermore, the RUC recommendations do not include a crosswalk to support the RUC-recommended work RVU. The RUC recommendations noted a lack of potential crosswalk codes due to the complete lack of similarly intense major surgical procedures comparable in the amount of skin-to-skin time, operating room time and amount of post-operative care. We note that the RUC-recommended work RVU of 13.15 is higher than similarly timed codes on the PFS. Given that lack of both survey data and a crosswalk to support the RUC-recommended work RVU for this new code, and that the RUC-recommended work RVU of 13.15 is higher than similarly timed codes on the PFS, we believe it is more appropriate to propose contractor-pricing for CPT code 66X01. We also note that the RUC recommended contractor-pricing for another code in this family, CPT code 66983, which we are proposing for CY 2020.

For CPT code 66X02, the RUC recommended a work RVU of 10.25, we disagree with the RUC-recommended work RVU and are proposing contractor-pricing for this code. In reviewing this code, we note that the RUC recommendation survey values do not support the RUC-recommended work RVU of 10.25. Furthermore, we are concerned with the RUC recommended crosswalk, CPT code 67110 (*Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopexy)*, which is the same crosswalk used to support the RUC-recommended work RVU of 10.25 for another code in this family, CPT code 66982. CPT code 67110 has 30 minutes of intraservice time and 196 minutes of total time. Although CPT code 67110 has the identical intraservice time to CPT codes 66982 and 66X02, we note that CPT code 67110 has 196 minutes of total time, which is 21 minutes less than the 175 minutes of total time of CPT code 66982, and 6 minutes less than the 202 minutes of total time of CPT Code 66X02. However, the RUC is recommending the same work RVU of 10.25 for CPT codes 66982 and 66X02, supported by the same crosswalk to CPT code 67110.

Given that lack of survey data and our concern for the RUC-recommended crosswalk to support the RUC-recommended work RVU of 10.25 for CPT code 66X02, we believe it is appropriate to propose contractor-pricing for CPT code 66X02. We also note that the RUC recommended contractor-pricing for another code in this family, CPT code 66983, which we are prosing for CY 2020.

We are proposing to remove all the direct PE inputs for CPT codes 66X01 and 66X02, given our proposal for contractor-pricing for these codes. We are proposing the RUC-recommended direct PE inputs for the other codes in this family.

(28) X-Ray Exam—Sinuses (CPT Codes 70210 and 70220)

CPT code 70210 (*Radiologic examination, sinuses, paranasal, less than 3 views*) and CPT code 70220 (*Radiologic examination, sinuses, paranasal, complete, minimum of 3 views*) were identified as potentially misvalued through a screen for

Medicare services with utilization of 30,000 or more annually. These two codes were first reviewed by the RUC in April 2018, but were subsequently surveyed by the specialty societies and reviewed again by the RUC in January 2019.

The RUC recommended a work RVU for CPT code 70210 of 0.20, which is a slight increase over the current work RVU for this code (0.17). The RUC's recommendation is consistent with 25th percentile of survey results and is based on a comparison of the survey code with the two key reference services. The first key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*), has a work RVU of 0.22, 4 minutes of intraservice time, and 6 minutes of total time. The RUC noted that the survey code has one minute less intraservice and total time compared with the first key reference service (CPT code 71046), which accounts for the slightly lower work RVU for the survey code. The RUC also compared CPT code 70210 to CPT code 70355 (*Orthopantogram (e.g., panoramic X-ray)*), with a work RVU of 0.20, 5 minutes of intraservice time, and 6 minutes of total time. Although the intraservice and total times are lower for CPT code 70210 than for CPT code 70355, the work is slightly more intense for the survey code, according to the RUC, justifying an identical work RVU of 0.20 for CPT code 70210. We disagree with the RUC's recommendation to increase the work RVU for CPT code 70210 from the current value (0.17) to 0.20 for two main reasons. First, the total time (5 minutes) for this code has not changed from the current total time and without a corresponding explanation for an increase in valuation despite maintaining the same total time, we do are not convinced that the work RVU for this code should increase. In addition, we note that based on a general comparison of CPT codes with identical intraservice time and total time (approximately 23 comparison codes, excluding those currently under review), a work RVU of 0.20 would establish a new upper threshold among this cohort. We are proposing to maintain the work RVU for CPT code 70210 of 0.17 work RVUs, bracketed by two services. On the upper side, we identified CPT code 73501 (*Radiologic examination, hip, unilateral, with pelvis when performed; 1 view*) with a work RVU of 0.18, and on the lower side, we identified CPT code 73560 (*Radiologic examination, knee; 1 or 2 views*) with a work RVU of 0.16. For CPT code 70220, we are proposing the RUC-recommended work RVU of 0.22.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(29) X-Ray Exam—Skull (CPT Codes 70250 and 70260)

CPT code 70250 (*Radiologic examination, skull, less than 4 views*) was identified as potentially misvalued through a screen of Medicare services with utilization of 30,000 or more annually. CPT code 70260 (*Radiologic examination, skull; complete, minimum of 4 views*) was included as part of the same family. These two codes were first reviewed by the RUC in April 2018, but were subsequently surveyed by the specialty societies and reviewed by the RUC again in January 2019.

The RUC-recommended work RVU for CPT code 70250 is 0.20, which is a slight decrease from the current work RVU for this code (0.24). The decrease, according to the RUC, reflects a slightly lower total time required to furnish the service (from 7 minutes to 5 minutes) and is consistent with the 25th percentile work RVU from the survey results. The RUC-recommended work RVU is bracketed by two CPT codes: Top key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*) with 4 minutes of intraservice time, 6 minutes total time, and a work RVU of 0.22; and key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*), with intraservice time of 4 minutes, total time of 6 minutes, and a work RVU of 0.18. The RUC noted that while the survey code has less time than CPT code 71046, the work is slightly more intense due to anatomical and contextual complexity. The survey code is also more intense compared with the second key reference service, CPT code 73562, according to the RUC, because of the higher level of technical skill involved in an X-ray of the skull (axial skeleton) compared with an X-ray of the knee (appendicular skeleton). The RUC further indicated that a comparison between the survey code and CPT codes with a work RVU of 0.18 would not be appropriate given the higher level of complexity associated with an X-ray of the skull than with other CPT codes that have similar times. We disagree with the recommended work RVU of 0.20 for CPT code 70250. The total time for furnishing the service has decreased by 2 minutes while the description of the work involved in furnishing the service has not changed. This suggests that a value closer to the total time ratio (TTR) calculation (0.17 work RVU) might be more appropriate. In addition, a search of CPT codes with 3 minutes of intraservice time and 5 minutes of total time indicates that the maximum work RVU for codes with these times is 0.18, meaning that a work RVU of 0.20 would establish a new relative high work RVU for codes with these times. We believe that a crosswalk to CPT code 73501 (*Radiologic examination, hip, unilateral, with pelvis when performed; 1 view*) with a work RVU of 0.18, 3 minutes of intraservice time, and 5 minutes of total time, accurately reflects both the time and intensity of furnishing the service described by CPT code 70250. Therefore, we are proposing a work RVU of 0.18 for CPT code 70250.

The RUC recommended a work RVU of 0.29 for CPT code 70260, which is lower than the current work RVU of 0.34. The survey times for furnishing the service are 4 minutes of intraservice time and 7 minutes total time, compared with the current intraservice time and total time of 7 minutes. However, in developing their recommendation, the RUC reduced the total time for this code from 7 minutes to 6 minutes. Although the RUC's recommended work RVU reflects the 25th percentile of survey results, the survey 25th percentile is based on an additional minute of total time compared with the RUC's total time for this CPT code. Moreover, since we are proposing a lower work RVU for the base code for this family (work RVU of 0.18 for CPT code 70250), we believe a lower work RVU for CPT code 70260 is warranted. To identify an alternative value, we calculated the increment between the current work RVU for CPT code 72050 (work RVU of 0.24) and the current work RVU for CPT code 72060 (work RVU of 0.34) and applied it to the CMS proposed work RVU for CPT code 70250 (0.18 + 0.10) to calculate a work RVU of 0.28. We believe that applying this increment is a better reflection of the work time and intensity involved in furnishing CPT code 70260. We are proposing a work RVU for CPT code 70260 of 0.28.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(30) X-Ray Exam—Neck (CPT Code 70360)

CPT code 70360 (*Radiologic examination; neck, soft tissue*) was identified as potentially misvalued through a screen of CPT codes with annual Medicare utilization of 30,000 or more. CPT code 70360 was first reviewed by the RUC in April 2018 but was subsequently surveyed by the specialty societies and reviewed by the RUC again in January 2019.

The RUC recommended a work RVU of 0.20 for CPT code 70360, which is an increase over the current work RVU

(0.17). To support their recommendation, the RUC cited the survey key reference service, CPT code 71046 (*Radiologic examination, chest; 2 views*), with a work RVU of 0.22, 4 minutes of intraservice time, and 6 minutes of total time. They noted that the key reference code has one minute higher intraservice and total time, accounting for the slightly higher work RVU compared with the survey code, CPT code 70360. The RUC also cited the second highest key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*) with a work RVU of 0.18, intraservice time of 4 minutes, and total time of 6 minutes. They noted that, while the survey code has lower intraservice time (3 minutes) and total time (5 minutes) compared with CPT code 73562, the survey code is more complex than the key reference service, thereby supporting a higher work RVU for the survey code (CPT code 70360) of 0.20. We do not agree with the RUC that the work RVU for CPT code 70360 should increase from 0.17 to 0.20. The total time for the CPT code, as recommended by the RUC (5 minutes), is unchanged from the existing total time. Without a corresponding discussion of why the current work RVU is insufficient, we do not agree that there should be an increase in the work RVU. Furthermore, although the RUC's recommendation is consistent with the 25th percentile of survey results for the work RVU, the total time from the survey results was 6 minutes, not the RUC-recommended time of 5 minutes. When we looked at CPT codes with identical times to the survey code for a crosswalk, we identified CPT code 73552 (*Radiologic examination, femur; minimum 2 views*), with a work RVU of 0.18. We believe this is a more appropriate valuation for CPT code 70360 and we are proposing a work RVU for this CPT code of 0.18.

We are proposing the RUC-recommended direct PE inputs for CPT code 70360.

(31) X-Ray Exam—Spine (CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120)

CPT codes 72020 (*Radiologic examination spine, single view, specify level*) *and 72072* (*Radiologic examination, spine; thoracic, 3 views*) were identified through a screen of CMS/Other Source codes with Medicare utilization greater than 100,000 services annually. The code family was expanded to include 10 additional CPT codes to be reviewed together as a group: CPT code 72040 (*Radiologic examination, spine, cervical; 2 or 3 views*), CPT code 72050 (*Radiologic examination, spine, cervical; 4 or 5 views*), CPT code 72052 (*Radiologic examination, spine cervical; 6 or more views*), CPT code 72070 (*Radiologic examination spine; thoracic, 2 views*), CPT code 72074 (*Radiologic examination, spine; thoracic, minimum of 4 views*), CPT code 72080 (*Radiologic examination, spine; thoracolumbar junction, minimum of 2 views*), CPT code 72100 (*Radiologic examination, spine, lumbosacral; 2 or 3 views*), CPT code 72110 (*Radiologic examination, spine, lumbosacral; minimum of 4 views*), CPT code 72114 (*Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views*), and CPT code 72120 (*Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views*). This family of CPT codes was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey these codes and the RUC reviewed them again in January 2019.

For the majority of CPT codes in this family, the RUC recommended a work RVU that is slightly different (higher or lower) than the current work RVU. Three CPT codes in this family are maintaining the current work RVU. We are proposing the RUC-recommended work RVU for all 12 CPT codes in this family as follows: CPT code 72020 (work RVU = 0.16); CPT code 72040 (work RVU = 0.22); CPT code 72050 (work RVU = 0.27); CPT code 72052 (work RVU = 0.30); CPT code 72070 (work RVU = 0.20); CPT code 72072 (work RVU = 0.23); CPT code 72074 (work RVU = 0.25); 72080 (work RVU = 0.21); CPT code 72100 (work RVU = 0.22); CPT code 72110 (work RVU =0.26); CPT code 72114 (work RVU = 0.30); and CPT code 72120 (work RVU = 0.22).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(32) CT-Orbit-Ear-Fossa (CPT Codes 70480, 70481, and 70482)

In October 2017, the RAW requested that AMA staff develop a list of CMS/Other codes with Medicare utilization of 30,000 or more. CPT code 70480 (*Computed tomography (CT), orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material*) was identified. In addition, the code family was expanded to include two related CT codes, CPT code 70481 (*Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material*) and CPT code 70482 (*Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material followed by contrast material(s) and further sections*). In 2018, the RUC recommended this code family be surveyed.

For CPT code 70840, we disagree with the RUC-recommended work RVU of 1.28 and propose instead a work RVU of 1.13. We are proposing a lower work RVU because 1.13 represents the commensurate 12 percent decrease in work time reflected in survey values. We reference the work RVUs of CPT codes 72128 (*Computed tomography, chest, spine; without dye*) and 71250 (*Computed tomography, thorax without dye*) both of which have the same intraservice time (that is, 15 minutes) as CPT code 70840 but longer total times (that is, 25 minutes versus 22 minutes). We believe that CPT code 72128 with a work RVU of 1.0 and CPT code 71250 with a work RVU of 1.16 more accurately reflect the relative work values of CPT code 70840.

We also disagree with the RUC-recommended work RVU of 1.13 for CPT code 70481. Instead, we are proposing a work RVU of 1.06 for CPT code 70481. As with CPT code 70840, we are proposing a lower work RVU for CPT code 70481 because a work RVU of 1.06 is commensurate with the 23 percent decrease in surveyed total time from 26 to 20 minutes. We believe CPT code 76641 (*Ultrasound, breast, unilateral*) with a work RVU of 0.73 and CPT code 70460 (*Computed Tomography, head or brain, without contrast*) with a work RVU of 1.13 serve as appropriate references for our proposed work RVU for CPT code 70841. Although CPT codes 76641 and 70460 have longer total times at 22 minutes and lower intraservice times at 12 minutes, we believe they better reflect the relative work value of CPT code 70481 with a proposed work RVU of 1.06, total time of 20 minutes, and intraservice time of 13 minutes.

For the third code in the family, CPT code 70482, we are proposing the RUC-recommended work RVU of 1.27.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(33) CT Spine (CPT Codes 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, and 72133)

CPT code 72132 (*Computed tomography, lumbar spine; with contrast material*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare

utilization of 30,000 or more. Eight other spine CT codes were identified as part of the family, and they were surveyed and reviewed together at the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU for eight of the nine codes in the family. We are proposing a work RVU of 1.22 for CPT code 72126 (*Computed tomography, cervical spine; with contrast material*), a work RVU of 1.27 for CPT code 72127 (*Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections*), a work RVU of 1.00 for CPT code 72128 (*Computed tomography, thoracic spine; without contrast material*), a work RVU of 1.22 for CPT code 72129 (*Computed tomography, thoracic spine; with contrast material*), a work RVU of 1.27 for CPT code 72130 (*Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections*), a work RVU of 1.00 for CPT code 72131 (*Computed tomography, lumbar spine; without contrast material*), a work RVU of 1.22 for CPT code 72132 (*Computed tomography, lumbar spine; with contrast material*), and a work RVU of 1.27 for CPT code 72133 (*Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections*).

We disagree with the RUC-recommended work RVU of 1.07 for CPT code 72125 (*Computed tomography, cervical spine; without contrast material*) and we are proposing a work RVU of 1.00 to match the other without contrast codes in the family. The cervical spine CT procedure described by CPT code 72125 shares the identical surveyed work time as the thoracic spine CT procedure described by CPT code 72128 and the lumbar spine CT procedure described by CPT code 72131, and we believe that this indicates that these three CPT codes should share the same work RVU of 1.00. Our proposed work RVU would also match the pattern established by the rest of the codes in this family, in which the contrast procedures (CPT codes 72126, 72129, and 72132) share a proposed work RVU of 1.22 and the without/with contrast procedures (CPT codes 72127, 72130, and 72133) share a proposed work RVU of 1.27.

We recognize that the RUC has stated that they believe CPT code 72125 to be a more complex study than CPT codes 72128 and 72131 because the cervical spine is subject to an increased number of injuries and there are a larger number of articulations to evaluate. This was the basis for their recommendation that this code should be valued slightly higher than the other without contrast codes. However, if CPT code 72125 has a more difficult patient population and requires a larger number of articulations to evaluate as compared to CPT codes 72128 and 72131, we do not understand why this was not reflected in the surveyed work times, which were identical for the three procedures. We believe that if the intensity of the procedure were higher due to these additional difficulties, it would be reflected in a longer surveyed work time. In addition, the survey respondents selected a higher work RVU for CPT code 72131 than CPT code 72125 at both the survey 25th percentile (1.20 to 1.18) and survey median values (1.39 to 1.28), which does not suggest that CPT code 72125 should be valued at a higher rate.

We also note that the surveyed intraservice work time for CPT code 72125 is decreasing from 15 minutes to 12 minutes, and we believe that this provides additional support for a slight reduction in the work RVU to match the other without contrast codes in the family. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of prior work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(34) X-Ray Exam—Pelvis (CPT Codes 72170 and 72190)

CPT code 72190 (*Radiologic examination, pelvis; complete, minimum of 3 views*) was identified as potentially misvalued through a screen of CMS/Other codes with Medicare utilization of 30,000 or more annually. CPT code 72170 (*Radiologic examination, pelvis; 1 or 2 views*) was added as part of the family. The RUC originally reviewed these two codes after specialty societies employed a crosswalk methodology to value work and PE. However, after we expressed concern about the use of this approach, the specialty society agreed to survey the codes and the RUC reviewed them again at the meeting in January 2019.

The RUC recommended a work RVU of 0.17 for CPT code 72170, which maintains the current value. For CPT code 72190, the RUC recommended a work RVU of 0.25, which is slightly higher than the current value (0.21). We are proposing the RUC-recommended values for these two CPT codes.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(35) X-Ray Exam—Sacrum (CPT Codes 72200, 72202, and 72220)

CPT code 72220 (*Radiologic examination, sacrum and coccyx, minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 annually. CPT codes 72200 (*Radiologic examination, sacroiliac joints; less than 3 views*) and 72202 (*Radiologic examination, sacroiliac joints; 3 or more views*) were also included for review as part of the same family of codes. These three codes were originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey these codes and the RUC reviewed them again in January 2019.

For CPT code 72200, the RUC is recommending a work RVU of 0.20, which is higher than the current work RVU (0.17). To support their recommendation, the RUC compared the survey code to the key reference service, CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views*), with a work RVU of 0.29, 5 minutes of intraservice time and 7 minutes of total time. The intraservice and total times for the key reference service are one minute higher than the survey code (*4 minutes intraservice time, 6 minutes total time for CPT code 72200*) and the survey code is less intense, according to the RUC, thereby supporting a slightly lower work RVU of 0.20 for CPT code 72200. The second key reference service is CPT code 73562 (*Radiologic examination, knee; 3 views*), with 4 minutes of intraservice time, 6 minutes of total time, and a work RVU of 0.18. The RUC noted that this second key reference service is less intense to furnish than the survey code, which justifies a slightly lower work RVU despite identical intraservice time (4 minutes) and total time (6 minutes). The

RUC supported their recommendation of a work RVU for CPT code 72200 of 0.20 with two bracketing codes: CPT code 93042 (*Rhythm ECG, 1–3 leads; interpretation and report only*) with work RVU of 0.15, and CPT code 70355 (*Orthopantogram (e.g. panoramic x-ray)*) with a work RVU of 0.20 (which is identical to the RUC-recommended work RVU for CPT code 72200 but has one additional minute of intraservice time). A work RVU of 0.20 is consistent with the work RVU estimated by the TTR and reflects the 25th percentile of survey results. Nevertheless, we do not agree that there is sufficient justification for an increase in work RVU for CPT code 72200. We are concerned that the large variation in specialty societies' survey times is indicative of differences in patient population, practice workflow, or even possibly some ambiguity associated with the survey vignette. We also note that the 25th percentile of survey results are based on the overall survey total time, which is 8 minutes, rather than the RUC's recommended 6 minutes. The time parameters for furnishing the service affect all other points of comparison for purpose of valuing the code, including TTR, identification of potential crosswalks, and increment calculations. We found no corresponding explanation for the variability in survey times, leading us to question why there should be an increase in work RVU from the current value. Therefore, we are proposing to maintain the current work RVU for CPT code 72200 at 0.17.

For CPT code 72202, the RUC recommended a work RVU of 0.26, which is considerably higher than the current work RUV for this code of 0.19. The RUC supported their recommendation with two key reference services. The first is CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views*) with 5 minutes intraservice time, 7 minutes total time, and a work RVU of 0.29. They note that this code has an additional minute for intraservice and total time compared with the survey code, reflecting the additional views associated with evaluating bilateral hip joints. The second key reference service is CPT code 73562 (*Radiologic examination, knee; 3 views*) with 4 minutes intraservice time, 6 minutes total time, and a work RVU of 0.18. The RUC notes that the survey code has the same times but requires more intensity and includes an additional view compared with the reference service, which justifies a higher work RVU for the survey code. We disagree with the RUC's recommended work RVU for CPT code 72202. Given that there is no change in the total time required to furnish the service and there is no corresponding description of an increase in the intensity of the work relative to the existing value, we do not believe an increase of 0.07 work RVUs is warranted. The TTR calculation yields a work RVU of .019, suggesting that a value closer to the current work RVU would be more appropriate. In addition, since we consider the RUC-recommended work RVU for this code as an incremental change from the prior code in this family, we believe that an increase of 0.06 over the proposed work RVU of 0.18 for CPT code 72200, which yields a work RVU of 0.23, is a better reflection of the time and intensity required to furnish CPT code 72202. Our proposed value work RVU of 0.23 is bracketed by CPT code 73521 (*Radiologic examination, hips, bilateral, with pelvis when performed; 2 views*) on the lower end (work RVU = .22), and CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*), on the higher end (work RVU = 0.27). CPT code 73521 has the same times as the survey code but describes a bilateral service with 2 views, which is slightly less intense. CPT code 74021 also has identical times but involves X-ray of the abdomen with 3 views, a slightly higher intensity than the survey code.

The RUC-recommended work RVU for CPT code 72220 is 0.20, which reflects an increase over the current work RVU for this code (0.17). The key reference service from the survey results is CPT code 73522 (*Radiologic examination, hips, bilateral, with pelvis when performed, 2–4 views*), with a work RVU of 0.29, 5 minutes intraservice time, and 7 minutes total time. The RUC noted that the recommended work RVU for CPT code 72220 has a lower value than the top key reference code (CPT code 73522) because of the shorter time and lower intensity involved in furnishing the survey code. The second highest key reference service, CPT code 73562 (*Radiologic examination, knee; 3 views*) has a work RVU of 0.18 with 4 minutes of intraservice time and 6 minutes of total time. The RUC notes that this second key reference service has a lower work RVU than the survey code despite having a slightly higher intraservice time and total time because it involves an X-ray of just one knee. We disagree with the RUC's recommended increase in the work RVU for CPT code 72220 from 0.17 to 0.20. We note that there is no change in the total time required to furnish the service. We also note that a work RVU of 0.20 for CPT code 72220 would place it near the maximum work RVU for CPT codes with identical intraservice time (3 minutes) and total time (5 minutes). Instead, we are proposing to maintain the work RVU for this service at 0.17, which is consistent with our proposal to maintain the current work RVU for CPT code 72200 at 0.17 as well.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(36) X-Ray Exam—Clavicle-Shoulder (CPT Codes 73000, 73010, 73020, 73030, and 73050)

CPT code 73030 (*Radiologic examination, shoulder; complete, minimum of 2 views*) was identified as potentially misvalued through a screen of services with more than 100,000 utilization annually. CPT codes 73000 (*Radiologic examination; clavicle, complete), 73010 (Radiologic examination; scapula, complete*), 73020 (*Radiologic examination, shoulder; 1 view*), and 73050 (*Radiologic examination, acromioclavicular joints, bilateral, with or without weighted distraction*) were included for review as part of the same family. We are proposing the RUC-recommended work RVUs for all five codes in this family as follows: CPT code 73000 (work RVU = 0.16); CPT code 73010 (work RVU = 0.17); CPT code 73020 (work RVU = 0.15); CPT code 73030 (work RVU = 0.18); and CPT code 73050 (work RVU = 0.18).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(37) CT Lower Extremity (CPT Codes 73700, 73701, and 73702)

CPT code 73701 (*Computed tomography, lower extremity; with contrast material(s)*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. Two other lower extremity CT codes were identified as part of the family, and they were surveyed and reviewed together at the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU for all three codes in this family. We are proposing a work RVU of 1.00 for CPT code 73700 (*Computed tomography, lower extremity; without contrast material*), a work RVU of 1.16 for CPT code 73701 (*Computed tomography, lower extremity; with contrast material(s)*), and a work RVU of 1.22 for CPT code 73702 (*Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(38) X-Ray Elbow-Forearm (CPT Codes 73070, 73080, and 73090)

CPT codes 73070 (*Radiologic examination, elbow; 2 views*) and 73090 (*Radiologic examination; forearm, 2 views*) were identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73080 (*Radiologic examination, elbow; complete, minimum of 3 views*) was included for review as part of the same code family. All three CPT codes in this family were originally valued by the specialty societies using a crosswalk methodology approved by the RUC research committee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the codes and the RUC reviewed them again at the meeting in January 2019. We are proposing the RUC-recommended work RVU for all three codes in this family as follows: CPT code 73070 (work RVU = 0. 16); CPT code 73080 (work RVU = 0.17); and CPT code 73090 (work RVU = 0.16).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(39) X-Ray Heel (CPT Code 73650)

CPT code 73650 (*Radiologic examination; calcaneous, minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73650 was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the code and the RUC reviewed it again in January 2019. For CPT code 73650, we are proposing the RUC-recommended work RVU of 0.16. We are also proposing the RUC-recommended direct PE inputs for CPT code 73650.

(40) X-Ray Toe (CPT Code 73660)

CPT code 73660 (*Radiologic examination; toe(s), minimum of 2 views*) was identified on a screen of CMS/Other source codes with Medicare utilization greater than 100,000 services annually. CPT code 73660 was originally valued by the specialty societies using a crosswalk methodology approved by the RUC Research Subcommittee. However, after we expressed concern about the use of this approach for valuing work and PE, the specialty society agreed to survey the code and the RUC reviewed it again in January 2019. We are proposing the RUC-recommended work RVU for this code of 0.13 for CPT code 73660. We are also proposing the RUC-recommended direct PE inputs for CPT code 73660.

(41) Upper Gastrointestinal Tract Imaging (CPT Codes 74210, 74220, 74230, 74X00, 74240, 74246, and 74X01)

These services were identified through a list of list of CMS/Other codes with Medicare utilization of 30,000 or more. The CPT Editorial Panel subsequently revised this code set in order to conform to other families of radiologic examinations.

We are proposing the RUC-recommended work RVUs of 0.59 for CPT code 74210 (*Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*), 0.60 for CPT code 74220 (*Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*), 0.70 for CPT code 74X00 (*Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study*), 0.53 for CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*), 0.80 for CPT code 74240 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*) 0.90 for CPT code 74246 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study, including glucagon, when administered*), and 0.70 for CPT code 74X01 (*Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; with small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure)*). We are also proposing the reaffirmed work RVU of 0.59 for CPT code 74210 (*Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*) and the reaffirmed work RVU of 0.53 for CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*).

For the direct PE clinical labor input CA021 ''Perform procedure/service—NOT directly related to physician work time,'' we note that no rationale was given for the RUC-recommended times for these codes, and we are requesting comment on the appropriateness of the RUC-recommended clinical labor times for this activity of 13 minutes, 13 minutes, 15 minutes, 15 minutes, 19 minutes, 22 minutes, and 15 minutes for CPT codes 74210, 74220, 74X00, 74230, 74240, and 74246, respectively. In addition, for CPT code 74230, we are proposing to refine the clinical labor times for the ''Prepare room, equipment and supplies'' (CA013) and ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity codes to the standard values of 2 minutes each, as well as to refine the equipment times to reflect these changes in clinical labor.

(42) Lower Gastrointestinal Tract Imaging (CPT Codes 74250, 74251, 74270, and 74280)

These services were identified through a list CMS/Other codes with Medicare utilization of 30,000 or more. We are proposing the RUC-recommended work RVUs of 0.81 for CPT code 74250 (*Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (e.g., barium) study*), 1.17 for CPT code 74251 (*Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; double-contrast (e.g., high-density barium and air via enteroclysis tube) study, including glucagon, when administered*), 1.04 for 74270 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study*), and 1.26 for CPT code 74280 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high density barium and air) study, including glucagon, when administered*).

For the direct PE clinical labor input CA021 ''Perform procedure/service—NOT directly related to physician work time,'' we note that no rationale was given for the recommended times for these codes, and we are requesting comment on the appropriateness of the RUC-recommended clinical labor times for this activity of 19 minutes, 30 minutes, 25 minutes, and 36 minutes for CPT codes 74250, 74251, 74270, and 74280, respectively. In addition, we are proposing to refine the equipment time for the room, radiographic-fluoroscopic (EL014) for CPT code 74250 to conform to our established standard for highly technical equipment and to match the rest of the codes in the family.

(43) Urography (CPT Code 74425)

The physician time and work described by CPT code 74425 (Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation) was combined with services describing genitourinary catheter procedures in CY 2016, resulting in CPT codes 50431 (*Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (e.g., ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access*) and 50432 (*Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation*). CPT code 74425 was not deleted at the time, but the RUC agreed with the specialty societies that 2 years of Medicare claims data should be available for analysis before the code was resurveyed for valuation to allow for any changes in the characteristics and process involved in furnishing the service separately from the genitourinary catheter procedures. The specialty society surveyed CPT code 74425 and reviewed the results with the RUC in October 2018.

The results of the specialty society surveys indicated a large increase in the amount of time required to furnish the service and, correspondingly, to the work RVU. The total time for CPT code 74425 based on the survey results was 34 minutes, an increase of 25 minutes over the current total time of 9 minutes. In reviewing the survey results, the RUC revised the total time for this CPT code to 24 minutes, with a recommended work RVU of 0.51. The reason for the large increase in time according to the RUC, is a change in the typical patient profile in which the typical patient is one with an ileal conduit through which nephrostomy tubes have been placed for post-operative obstruction. Based on the described change in patient population and increased time required to furnish the service, we are proposing the RUC-recommended work RVU of 0.51 for CPT code 74425.

We are proposing the RUC-recommended direct PE inputs for CPT code 74425.

(44) Abdominal Aortography (CPT Codes 75625 and 75630)

In October 2017, the RAW requested that AMA staff compile a list of CMS/Other codes with Medicare utilization of 30,000 or more. In January 2018, the RUC recommended to survey these services for the October 2018 RUC meeting. Subsequently, the specialty society surveyed these codes.

We disagree with the RUC-recommended work RVU of 1.75 for CPT code 75625 (*Aortography, abdominal, by serialography, radiological supervision and interpretation*). In reviewing CPT code 75625, we note that the key reference service, CPT Code 75710 (*Angiography, extremity, unilateral, radiological supervision and interpretation*), has 10 additional minutes of intraservice time, 10 additional minutes of total time and the same work RVU, which would indicate the RUC-recommended work RVU of 1.75 appears to be overvalued. When we compared the intraservice time ratio between the RUC-recommended time of 30 minutes and the reference code intraservice time of 40 minutes we found a ratio of 25 percent. 25 percent of the reference code work RVU of 1.75 equals a work RVU of 1.31. When we compared the total service time ratio between the RUC-recommended time of 60 minutes and the reference code total service time of 70 minutes we found a ratio of 14 percent. 14 percent of the reference code work RVU of 1.75 equals a work RVU of 1.51. Therefore, we believe an accurate value would lie between 1.31 and 1.52 RVUs. In looking for a comparative code, we have identified CPT code 38222. CPT Code 38222 is a recently reviewed CPT code with the identical intraservice and total times. As a result, we believe that it is more accurate to propose a work RVU of 1.44 based on a crosswalk to CPT code 38222.

In case of CPT code 75630 (*Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation*), we are proposing the RUC-recommended value of 2.00 RVUs.

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(45) Angiography (CPT Codes 75726 and 75774)

We are proposing the RUC-recommend work RVU for both codes in this family. We are proposing a work RVU of 2.05 for CPT code 75726 (*Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation*), a work RVU of 1.01 for CPT code 75774 (*Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure*).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(46) X-Ray Exam Specimen (CPT Code 76098)

CPT code 70098 was reviewed by the RUC based on a request from the American College of Radiology (ACR) to determine whether CPT code 76098 was undervalued because of the assumption that the service is typically furnished concurrently with a placement of localization device service (CPT codes 19281 through 19288 each representing a different imaging modality). In a letter to the RUC, ACR expressed concern about the appropriateness of a codes valuation process in which physician time and intensity for a code are reduced to account for overlap with codes that are furnished to a patient on the same day. During the April 2018 RUC meeting, the specialty societies requested a work RVU of 0.40 for CPT code 76098, with intraservice time of 5 minutes and total time of 15 minutes. Currently, this service has a work RVU of 0.16, with 5 minutes of total time and no available intraservice time. In April 2018, the RUC and the specialty society agreed that additional analysis of the data was warranted in consideration of the relatively large change in survey time and work RVU for this service. The RUC agreed to review the CPT code (CPT code 76098) again in October 2018.

The RUC recommended a work RVU, based on the October 2018 meeting, of 0.31 for CPT code 76098, which represents an increase over the current value (0.16) but a decrease relative to the specialty society's original request of 0.40. The intraservice time for this CPT code is 5 minutes, and the total time is 11 minutes. Based on the parameters we

typically use to review and evaluate RUC recommendations, which rely heavily on survey data, we agree that a work RVU of 0.31 for a CPT code with 5 minutes intraservice and 11 minutes total time is consistent with other CPT codes with similar times and levels of intensity. We are proposing the RUC-recommended work RVU for CPT code 76098 of 0.31.

We share the ACR's interest in establishing or clarifying parameters that indicate when CPT codes that are furnished concurrently by the same provider should be valued to account for the overlap in physician work time and intensity, and even PE. We are broadly interested in stakeholder feedback and suggestions about what those parameters might be and whether or how they should affect code valuation.

We are proposing the RUC-recommended direct PE inputs for CPT code 76098.

(47) 3D Rendering (CPT Code 76376)

CPT code 76376 (*3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation*) was identified as potentially misvalued on a screen of codes with a negative intraservice work per unit of time (IWPUT), with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. It was surveyed and reviewed at the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.20 for CPT code 76376. We are also proposing the RUC-recommended direct PE inputs for CPT code 76376.

(48) Ultrasound Exam—Chest (CPT Code 76604)

CPT code 76604 (*Ultrasound, chest (includes mediastinum), real time with image documentation*) was identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. It was surveyed and reviewed for the April 2018 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.59 for CPT code 76604. We are also proposing the RUC-recommended direct PE inputs for CPT code 76604.

(49) X-Ray Exam—Bone (CPT Codes 77073, 77074, 77075, 77076, and 77077)

CPT codes 77073 (*Bone length studies (orthoroentgenogram, scanogram)*), 77075 (*Radiologic examination, osseous survey; complete (axial and appendicular skeleton)*), and 77077 (*Joint survey, single view, 2 or more joints*) were identified as potentially misvalued on a screen of CMS/Other codes with Medicare utilization of 30,000 or more. CPT codes 77074 (*Radiologic examination, osseous survey; limited (e.g., for metastases)*) and 77076 (*Radiologic examination, osseous survey, infant*) were reviewed as part of the same family.

We are proposing the RUC-recommended work RVUs for all five CPT codes in this family as follows: CPT code 77073 (work RVU = 0.26); CPT code 77074 (work RVU = 0.44); CPT code 77075 (work RVU = 0.55); CPT code 77076 (work RVU = 0.70); and CPT code 77077 (work RVU = 0.33).

We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(50) SPECT–CT Procedures (CPT Codes 78800, 78801, 78802, 78803, 78804, 788X0, 788X1, 788X2, and 788X3)

The CPT Editorial Panel revised five codes, created four new codes and deleted nine codes to better differentiate between planar radiopharmaceutical localization procedures and SPECT, SPECT–CT and multiple area or multiple day radiopharmaceutical localization/distribution procedures.

For CPT code 78800 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar limited single area (e.g., head, neck, chest pelvis), single day of imaging*), we disagree with the RUC recommendation to assign a work RVU of 0.70 based on the survey 25th percentile to this code, because we believe that it is inconsistent with the RUC-recommended reduction in physician time. We are proposing a work RVU of 0.64 based on the following total time ratio: The RUC-recommended 27 minutes divided by the current 28 minutes multiplied by the current work RVU of 0.66, which results in a work RVU of 0.64. We note that this value is bracketed by the work RVUs of CPT code 93287 (*Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system*), with a work RVU of 0.45, and CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*), with a work RVU of 0.70. Both of these supporting crosswalks have intraservice time values of 10 minutes, and they have similar total time values.

For CPT code 78801 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, 2 or more areas (e.g., abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days*), we disagree with the RUC recommendation to maintain the current work RVU of 0.79 despite a 22-minute reduction in intraservice time. We believe a reduction from the current value is warranted given the recommended reduction in physician time, and also to be consistent with other services of similar time values. We are proposing a work RVU of 0.73 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.09 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 0.73, we note that it falls between the work RVUs of CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*) with a work RVU of 0.70, and CPT code 93280 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead pacemaker system*) with a work RVU of 0.77.

For CPT code 78802 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, single day of imaging*), we disagree with the RUC recommendation to maintain the current work RVU of 0.86, as we believe that it is inconsistent with a reduction in time values, and because we do not agree that a work RVU that is among the highest of other services of similar intraservice time values is appropriate. We are proposing a work RVU of 0.80 based on the RUC-recommended incremental

relationship between this code and CPT code 78800 (a difference of 0.16 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 0.80, we note that it falls between the work RVUs of CPT code 92520 (*Laryngeal function studies (i.e., aerodynamic testing and acoustic testing)*) with a work RVU of 0.75, and CPT code 93282 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system*) with a work RVU of 0.85.

For CPT code 78804 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); planar, whole body, requiring 2 or more days of imaging*), we disagree with the RUC recommendation to maintain the current work RVU of 1.07, as we believe that it is inconsistent with a reduction in time values, and because this work RVU appears to be valued highly relative to other services of similar time values. We are proposing a work RVU of 1.01 based on the RUC-recommended incremental relationship between this code and CPT code 78800 (a difference of 0.37 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.01, we reference CPT code 91111 (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report*), which has a work RVU of 1.00 and similar physician time values.

For CPT code 78803 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), single area (e.g., head, neck, chest pelvis), single day of imaging*), we disagree with the RUC recommendation to increase the work RVU to 1.20 based on the survey 25th percentile to this code, because we believe that it is inconsistent with the RUC-recommended reduction in physician time. We are proposing to maintain the current work RVU of 1.09. We support this value with a reference to CPT code 78266 (*Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days*), which has a work RVU of 1.08, and similar time values.

For CPT code 788X0 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (e.g., head, neck, chest or pelvis), single day of imaging*), we disagree with the RUC recommendation to assign a work RVU of 1.60 based on the survey 25th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we are proposing a work RVU of 1.49 for CPT code 788X0 based on the RUC-recommended incremental relationship between CPT code 788X0 and CPT code 78803 (a difference of 1.09 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.49, we note that it is bracketed by the work RVUs of CPT codes 72195 (*Magnetic resonance (e.g., proton) imaging, pelvis; without contrast material(s)*) with a work RVU of 1.46, and 95861 (*Needle electromyography; 2 extremities with or without related paraspinal areas*) with a work RVU of 1.54. The physician time values of these services bracket those recommended for CPT code 778X0.

For CPT code 788X1 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT), minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days*), we disagree with the RUC recommendation to assign a work RVU of 1.93 based on the survey 50th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we are proposing a work RVU of 1.82 based on the RUC-recommended incremental relationship between this code and CPT code 78803 (a difference of 0.73 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 1.82, we note that it is bracketed by the work RVUs of the CPT codes which are members of the same code families referenced for the previous CPT code, 788X0: CPT codes 72191 (*Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing*) with a work RVU of 1.81, and 95863 (*Needle electromyography; 3 extremities with or without related paraspinal areas*) with a work RVU of 1.87. The physician time values of these services bracket those recommended for CPT code 778X1.

For CPT code 788X2 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s), (includes vascular flow and blood pool imaging when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging*), we disagree with the RUC recommendation to assign a work RVU of 2.23 based on the survey 50th percentile to this code, as this would value this code more highly than services of similar time values. To maintain relativity among services in this family, we are proposing a work RVU of 2.12 based on the RUC-recommended incremental relationship between this code and CPT code 78803 (a difference of 1.03 RVU), which we apply to our proposed value for the latter code. As support for our proposed work RVU of 2.12, we reference CPT code 70554 (*Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration*), which has a work RVU of 2.11 and physician intraservice and total time values that are identical to those recommended for this service.

For CPT code 788X3 (*Radiopharmaceutical quantification measurement(s) single area*), we disagree with the RUC recommendation to assign a work RVU of 0.51 based on the survey 25th percentile to this code, because we wish to maintain relativity and proportionality among codes of this family. We based our values for the other codes in this family on their relative relationship to either CPT code 78800 or 788X2, depending on the type of service described by the code. For CPT code 788X0, which describes a single day of imaging and is thus analagous to CPT code 788X3 in terms of units of service, our analysis indicates a reduction from the RUC value of approximately 7 percent is appropriate. Therefore, we apply a

similar reduction of 7 percent to the RUC-recommended work RVU of 0.51 to arrive at an RVU of 0.47. We support this value by noting that it is bracketed by add-on CPT codes 77001 (*Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (List separately in addition to code for primary procedure)*) with a work RVU of 0.38, and 77002 (*Fluoroscopic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device) (List separately in addition to code for primary procedure)*), with a work RVU of 0.54. Both of these reference CPT codes have intraservice time values that are similar to, and total time values that are identical to, those recommended for CPT code 788X3.

For the direct PE inputs, we are refining the number of minutes of clinical labor allocated to the activity ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' to the 2-minute standard for CPT codes 78800, 78801, 78802, 78804, 78803, 788X0, 788X1, and 788X2, as no rationale was provided for these codes to have times above the standard for this activity. We are also refining the equipment time formulas to reflect this clinical labor refinement for these codes. For CPT codes 78800, 78801, 78802, 78804, 78803, 788X0, 788X1, and 788X2, we are proposing to refine the equipment times to match our standard equipment time formula for the professional PACS workstation. For the supply item SM022 ''sanitizing cloth-wipe (surface, instruments, equipment),'' we are refining these supplies to quantities of 5 each for CPT codes 78801, 78804, and 788X2 to conform with other codes in the family.

(51) Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35)

CPT code 78492 was identified via the High Volume Growth screen with total Medicare utilization over 10,000 that increased by at least 100 percent from 2009 through 2014. The CPT Editorial Panel revised this code set to reflect newer technology aspects such as wall motion, ejection fraction, flow reserve, and technology updates for hardware and software. The CPT Editorial Panel deleted a Category III code, added six Category I codes, and revised the three existing codes to separately identify component services included for myocardial imaging using positron emission tomography.

For CPT code 78491 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic)*), we disagree with the RUC-recommended work RVU of 1.56, which is the survey 25th percentile value, as we believe that the 30-minute reduction in intraservice time and 15-minute reduction in physician total time does not validate an increase in work RVU, and we believe that the significance of the reductions in recommended physician time values warrants a reduction in work RVU. We are proposing a work RVU of 1.00 based on the following total time ratio: The recommended 30 minutes divided by the current 45 minutes multiplied by the current work RVU of 1.50, which results in a work RVU of 1.00. As further support for this value, we note that it falls between CPT code 78278 (*Acute gastrointestinal blood loss imaging*), with a work RVU of 0.99, and CPT code 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), with a work RVU of 1.03.

For CPT code 78X31 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan*), we disagree with the RUC recommendation of 1.67 based on the survey 25th percentile, as we do not agree this service would be appropriately valued with an RVU that is among the highest of all services of similar times with this global period. We are proposing a work RVU of 1.11 by applying the RUC-recommended increment between CPT code 78491 and this code, an increment of 0.11, to our proposed value of 1.00 for CPT code 78491, thus maintaining the RUC's recommended incremental relationship between these codes. As further support for this value, we note that it falls between CPT codes 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters*) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional)), with a work RVU of 0.97, and CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*), with a work RVU of 1.25; both of these codes have similar physician time values.

For CPT code 78459 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study*), we disagree with the RUC recommendation to increase the work RVU to 1.61 based on the survey 25th percentile. We believe that the magnitude of the recommended reductions in physician time (a 50-minute reduction in intraservice time and a 32-minute reduction in total time) suggests that this value is overestimated; furthermore, we note that the RUC's recommendation is among the highest for all XXX-global period codes with similar time values. We are proposing a work RVU of 1.05 by applying the RUC-recommended increment between this code and CPT code 78491, a difference of 0.05, which we apply to our proposed value for the latter code. We support our RVU of 1.05 by referencing two CPT codes: 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*), and 36440 (*Push transfusion, blood, 2 years or younger*), both of which have work RVUs of 1.03, as well as identical intraservice and similar total time values.

We disagree with the RUC's recommended valuation of 1.76 for CPT code 78X29 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study; with concurrently acquired computed tomography transmission scan*), which is based on the survey 25th percentile, because we believe a work RVU that is greater than those of all other services of similar intraservice time values is not appropriate. We are proposing a work RVU of 1.20 for CPT code 78X29. We are proposing to value CPT code 78X29 with an incremental methodology, which preserves the RUC-recommended relationship among the codes in this family; the RUC

recommends an increment of 0.20 between CPT code 78X29 and CPT code 78491. We are proposing to apply this increment to our proposed value of 1.00 for CPT code 78491 to arrive at our value of 1.20.

We disagree with the RUC's recommendation of 1.80 for CPT code 78492 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); multiple studies at rest and stress (exercise or pharmacologic)*) given the magnitude of the recommended reduction in physician time values (a 35-minute reduction in intraservice time and a 17-minute reduction in total time), and also given the fact that the RUC's recommended value would be the highest of all codes of this intraservice time and global period. We are proposing a work RVU of 1.24 based on the RUC-recommended incremental difference between 78491 and 78492 of 0.24, which we add to our proposed value for 78491 for a work RVU of 1.24. As further support for this value, we reference CPT code 95908 (*Nerve conduction studies; 3–4 studies*), with a work RVU of 1.25, similar physician time values.

We disagree with the RUC's recommendation of 1.90 for CPT code 78X32 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan*) which is based on a crosswalk to CPT code 64617 (*Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed*), because the fact that this work RVU that is greater than those of all other services of similar intraservice time values suggests that it is an overestimate. Instead we are proposing a work RVU of 1.34 for CPT code 78X32, based on an incremental methodology. We apply the RUC-recommended increment between 78491 and CPT code 78X32, a difference of 0.34, to our proposed value of 1.00 for CPT code 78491, for a value of 1.34. We support this value by referencing CPT code 77261 (*Therapeutic radiology treatment planning; simple*), with a work RVU of 1.30, and CPT code 94003 (*Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day*), with a work RVU of 1.37. These codes have similar physician time values.

We disagree with the RUC's recommendation of 2.07 for CPT code 78X33 (*Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (e.g., myocardial viability)*), because we believe the fact that this work RVU is greater than those of all other services of similar intraservice time values suggests that it is an overestimate. We are proposing a work RVU of 1.51 for CPT code 78X33, based on an incremental methodology. We apply the RUC-recommended increment between 78491 and CPT code 78X33, a difference of 0.51, to our proposed value of 1.00 for CPT code 78491, for a value of 1.51. We support this value by referencing CPT code 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*), with a work RVU of 1.46, and similar physician time values.

Similarly for CPT code 78X34 (*Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan*), we disagree with the RUC's recommendation of 2.26 based on a crosswalk to CPT code 71552 (*Magnetic resonance (e.g., proton) imaging, chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences*), because we believe the fact that this work RVU is among the highest among services of similar intraservice time values suggests that it is an overestimate. We are proposing a work RVU of 1.70 by applying the RUC-recommended increment between CPT code 78X34 and CPT code 78491, which is a difference of 0.70, to our proposed value for CPT code 78491 for a value of 1.70. We support this value by referencing CPT codes 95924 (*Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt*) and 74182 (*Magnetic resonance (e.g., proton) imaging, abdomen; with contrast material(s)*), both of which have work RVUs of 1.73.

For CPT code 78X35 (*Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography, rest and pharmacologic stress (List separately in addition to code for primary procedure)*), we disagree with the RUC recommendation to assign a work RVU of 0.63 to this code based on the survey 25th percentile, because we believe a comparison to other codes with a global period of ZZZ suggests that this is somewhat overvalued, and because we wish to maintain relativity and proportionality to other codes in this series. We based our values for the other codes in this family on their relative relationships to CPT code 78491; for that code our analysis indicates that a reduction from the RUC value of roughly ⅓ is appropriate, based on a ratio of the decrease in total time to the current work RVU. Therefore, we apply a similar reduction of ⅓ to the RUC-recommended work RVU of 0.63 to arrive at an RVU of approximately 0.42. Applying a reduction that is similar to the reduction we think is warranted from the RUC value for CPT code 78491 to CPT code 78X35 will maintain consistency in value among these services. We believe this work RVU is validated by noting that it is bracketed by CPT codes 15272 (*Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), with a work RVU of 0.33, and 11105 (*Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)*), with a work RVU of 0.45. A work RVU of 0.42 is thus consistent with ZZZ global period codes of similar physician times.

For the direct PE inputs, for several of the equipment items, we are proposing to refine the equipment times to conform to our established policies for non-highly, as well as for highly technical equipment. In addition, we are proposing to refine the equipment times to conform to our established policies for PACS Workstation. For the new equipment items ER110: ''PET Refurbished Imaging Cardiac Configuration'' and ER111: ''PET/CT Imaging Camera Cardiac Configuration,'' we are proposing to assume that a 90 percent equipment utilization rate is typical, as this would be consistent with our equipment utilization assumptions for expensive diagnostic imaging equipment. For the supply item SM022 ''sanitizing cloth-wipe (surface, instruments, equipment),'' we are refining these supplies to quantities of 5 each for CPT codes 78X33 and 78X34 to conform with other codes in the family. We are proposing that we will

not price the ''Software and hardware package for Absolute Quantitation'' as a new equipment item, due to the fact that the submitted invoices included a service contract and a combined software/hardware bundle with no breakdown on individual pricing. Based on our lack of specific pricing data, we believe that this software is more accurately characterized as an indirect PE input that is not individually allocable to a particular patient for a particular service.

(52) Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001)

CPT code 88141 (*Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician*), HCPCS code G0124 (*Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician*), HCPCS code G0141 (*Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician*), and HCPCS code P3001 (*Screening Papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician*) were identified as potentially misvalued on a list of CMS or other source codes with Medicare utilization of 30,000 or more.

In the CY 2000 PFS final rule (64 FR 59408), we finalized a policy that it was more appropriate to evaluate the work, PE, and MP RVUs for HCPCS codes P3001, G0124, and G0141 identical or comparable to the values of CPT code 88141.

For CY 2020, the RUC recommended a work RVU of 0.42 for CPT code 88141 and HCPCS codes G0124, G0141, and P3001, based on the current value. We disagree with the RUC-recommended work RVU and are proposing a work RVU of 0.26 for all four codes in this family, based on our time ratio methodology and a crosswalk to CPT code 93313 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only*), which has an identical work RVU of 0.26, identical intraservice and total work times values to CPT code 88141 and HCPCS codes G0124, and G0141, and similar intraservice and total time values to HCPCS code P3001.

In reviewing this family of codes, we note that the intraservice and total work times for CPT code 88141 and HCPCS codes G0124, and G0141 are decreasing from 16 minutes to 10 minutes (38 percent reduction) and the intraservice and total work times for HCPCS code P3001 are decreasing from 16 minutes to 12 minutes (25 percent reduction). However, the RUC recommended a work RVU of 0.42 for all four codes in this family, based on the maintaining the current work RVU. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 88141 and HCPCS codes G0124, G0141, and P3001, we believe that it would be more accurate to propose a work RVU of 0.26, based on our time ratio methodology and a crosswalk to CPT code 93313 to account for these decreases in the surveyed work times.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Perform regulatory mandated quality assurance activity'' (CA033) activity from 7 minutes to 5 minutes for all four codes in the family. We believe that these quality assurance activities would not typically take 7 minutes to perform, given that similar federally mandated MQSA activities were recommended and finalized at a time of 4 minutes for CPT codes 77065–77067 in CY 2017 (81 FR 80314–80316), and other related regulatory compliance activities were recommended and finalized at a time of 5 minutes for CPT codes 78012–78014 in CY 2013 (77 FR 69037). To preserve relativity between services, we are proposing a clinical labor time of 5 minutes for the codes in this family based on this prior allocation of clinical labor time.

We are also proposing to remove the 1-minute of clinical labor time for the ''File specimen, supplies, and other materials'' (PA008) activity from all four codes under the rationale that this task is a form of indirect PE. As we stated in the CY 2017 PFS final rule (81 FR 80324), we agree that filing specimens is an important task, and we agree that these would take more than zero minutes to perform. However, we continue to believe that these activities are correctly categorized under indirect PE as administrative functions, and therefore, we do not recognize the filing of specimens as a direct PE input, and we do not consider this task as typically performed by clinical labor on a per-service basis.

We are proposing to refine the equipment time for the compound microscope (EP024) equipment to 10 minutes for all four codes in the family to match the work time of the procedures. The recommended materials for this code family state that the compound microscope is utilized by the pathologist, and therefore, we believe that the 10-minute work time of the procedures would be the most accurate equipment time to propose.

(53) Biofeedback Training (CPT Codes 908XX and 909XX)

CPT code 90911 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry*) was identified as potentially misvalued on a RAW screen of codes with a negative IWPUT and Medicare utilization over 10,000 for all services or over 1,000 for Harvard valued and CMS or other source codes. In September 2018, the CPT Editorial Panel replaced this code with two new codes to describe biofeedback training initial 15 minutes of one-on-one patient contact and each additional 15 minutes of biofeedback training.

We are proposing the RUC-recommended work RVU of 0.90 for CPT code 908XX (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; initial 15 minutes of one-on-one patient contact*), as well as the RUC-recommended work RVU of 0.50 for CPT code 909XX (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry when performed; each additional 15 minutes of one-on-one patient contact*). For the direct PE inputs, we are proposing to refine the equipment time for the power table (EF031) equipment in CPT code 908XX to conform to our established standard for non-highly technical equipment.

We are also proposing to designate CPT codes 908XX and 909XX as ''sometimes therapy'' procedures which means that an appropriate therapy modifier is always required when this service is furnished by therapists. For more information we direct readers to the Therapy Code List section of the CMS website at *https://www.cms.gov/Medicare/Billing/TherapyServices/AnnualTherapyUpdate.html*.

(54) Corneal Hysteresis Determination (CPT Code 92145)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the AMA/Specialty Society RVS Update Committee. The AMA RUC reviewed this service at the October 2018 RAW meeting, and indicated that the

utilization is continuing to increase for this service. This code was surveyed and reviewed for the January 2019 RUC meeting.

We are proposing the work RVU of 0.10 as recommended by the RUC. We are also proposing the RUC-recommended direct PE inputs for CPT code 92145 without refinement.

(55) Computerized Dynamic Posturography (CPT Codes 92548 and 92XX0)

CPT code 92548 (*Computerized dynamic posturography*) was identified via the negative IWPUT screen. CPT revised one code and added another code to more accurately describe the current clinical work and equipment necessary to provide this service.

We do not agree with the RUC's recommended work RVUs of 0.76 for CPT code 92548 (*Computerized dynamic posturography sensory organization test (CDP–SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report*), or 0.96 for CPT code 92XX0 (*Computerized dynamic posturography sensory organization test (CDP–SOT), 6 conditions (i.e., eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)*). For CPT code 92548, we agree that an increase in work RVU is warranted; however, we believe the surveyed time values suggest an increase of a less significant magnitude than that recommended. We are proposing a work RVU of 0.67 based on the intraservice time ratio: we divide the RUC-recommended intraservice time value of 20 by the current value of 15 and multiply the product by the current work RVU of 0.50 for a ratio of 0.67. As a supporting crosswalk, we note that our value is greater than the work RVU of 0.60 for CPT code 93316 (*Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only*), which has identical intraservice and total times.

We are proposing to maintain relativity between these two codes by valuing CPT code 92XX0 by applying the RUC-recommended incremental difference between the two codes, a difference of 0.20, to our proposed value of 0.66 for CPT code 93316; therefore, we are proposing a work RVU of 0.87 for CPT code 92XX0. As further support for this value, we note that it falls between the work RVUs of CPT codes 95972 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), with a work RVU of 0.80, and CPT code 38207 (*Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage*), with a work RVU of 0.89.

We are proposing the RUC-recommended direct PE inputs for these codes without refinement.

(56) Auditory Function Evaluation (CPT Codes 92626 and 92627)

CPT code 92626 (*Evaluation of auditory function for surgically implanted device(s), candidacy or post-operative status of a surgically implanted device(s); first hour*) appeared on the RAW 2016 high volume growth screen. In 2017, it was identified through a CMS request. CPT code 92627 (*Evaluation of auditory function for surgically implanted device(s), candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes*) the add-on code for CPT code for 92626, also was included in the CMS request to review audiology services.

For CY 2020, we are proposing the HCPAC-recommended work RVU of 1.40 for CPT code 92626, which is identical to its current RVU. We are also proposing the HCPAC-recommended work RVU of 0.33 for the add-on code, CPT code 92627. We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(57) Septostomy (CPT Codes 92992 and 92993)

CPT codes 92992 (*Atrial septectomy or septostomy; transvenous method, balloon (e.g., Rashkind type) (includes cardiac catheterization)*) and 92993 (*Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)*) were nominated as potentially misvalued services. These services are typically performed on children, a non-Medicare population, and are currently contractor-priced. These codes were surveyed and reviewed for the January 2019 RUC meeting.

We are proposing to maintain contractor pricing for CPT codes 92992 and 92993, as recommended by the RUC. These codes will be referred to the CPT Editorial Panel for revision and potential deletion. We are also proposing a change from 90-day to 0-day global period status for these two procedures, also as recommended by the RUC.

(58) Opthalmoscopy (CPT Codes 92X18 and 92X19)

CPT code 92225 was identified as potentially misvalued on a screen of codes with a negative IWPUT, with 2016 estimated Medicare utilization over 10,000 for RUC reviewed codes and over 1,000 for Harvard valued and CMS/Other source codes. In February 2018, the CPT Editorial Panel deleted CPT codes 92225 and 92226 and created two new codes to specify what portion of the eye is examined for a service beyond the normal comprehensive eye exam.

We are proposing the RUC-recommended work RVUs of 0.40 for CPT code 92X18 (*Ophthalmoscopy, extended, with retinal drawing and scleral depression of peripheral retinal disease (e.g., for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral*) and 0.26 for CPT code 92X19 (*Ophthalmoscopy, extended, with drawing of optic nerve or macula (e.g., for glaucoma, macular pathology, tumor) with interpretation and report, unilateral or bilateral*).

We are proposing the RUC-recommended direct PE inputs for this code family without refinement.

(59) Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299, and HCPCS Code GTTT1)

When the RUC previously reviewed the CPT code 93299 at the January 2017 RUC meeting, the specialty society submitted PE inputs for CPT code 93299 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisitions(s), receipt of transmissions and technician review, technical support and distribution of results*); the PE Subcommittee and RUC accepted the society recommendations. In the CY 2018 PFS final rule (82 FR 53064), we did not finalize our proposal to establish national pricing for CPT code 93299 and the code remained contractor-priced.

At the October 2018 RUC meeting, the RUC re-examined CPT code 93299. CPT codes 93297 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic*

monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional) and 93298 (*Interrogation device evaluation(s), remote up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis or recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional*) were added to this family of services. These three codes were reviewed for practice expense only.

CPT codes 93297 and 93298 are work-only codes and CPT code 93299 is meant to serve as the catch-all for both 30-day remote monitoring services. The RUC is unclear why the code family was designed this way, noting it may have been a way to allow for the possibility that the technical work would be provided by vendors, but they noted that this is not how the service is currently provided. Stating that in the decade since these codes were created, it has become clear that implantable cardiovascular monitor (ICM) and implantable loop recorder (ILR) services are very different and the PE cannot be appropriately captured for both services in a single technical code. They noted that CPT codes 93297–93299 will be placed on the new technology/new services list and be re-reviewed by the RUC in 3 years to ensure correct calculation and utilization assumptions. It was noted in the RUC recommendations that the specialty society intended to submit a coding proposal to the CPT Editorial Panel to delete CPT code 93299, as it will no longer be necessary to have a separate code for PE if CPT codes 93297 and 93298 are allocated direct PE in CY 2020.

In our review of these services, we note that the RUC recommendations did not provide a detailed description of the clinical labor tasks being performed or detailed information on the typical use of the supply and equipment used when furnishing these services. These details are important in order for us to review if the RUC-recommended PE inputs are appropriate to furnish these services. The RUC submitted PE inputs (which were not previously included) for the work-only CPT codes 93297 and 93298, but did not include details to substantiate these recommended PE inputs for any of the three codes in this family.

Additionally, we are concerned with the appropriateness of the RUC's reference code, CPT code 93296 (*Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*). CPT code 93296 is for remote monitoring over a 90-day period, but was used as a reference to derive the RUC-recommended direct PE inputs for CPT codes 93297–93299, which are for remote monitoring over a 30-day period.

For the CY 2020 direct PE inputs, we are proposing to remove the clinical labor time for ''Perform procedure/service—not directly related to physician work time'' (CA021); to remove the requested quantity for the supply ''Paper, laser printing (each sheet)'' (SK057); and to refine the equipment times in accordance with our standard equipment time formulas for CPT codes 93297 and 93298.

Although we are not proposing to allocate direct PE inputs for CPT codes 93297 and 93298, we are seeking additional comment on the appropriateness of CPT code 93296 as the reference code, details on the clinical labor tasks, and more information on the typical use of the supply and equipment used to furnish these services. For example, it was unclear in the RUC recommendations how many patients are monitored concurrently. As an additional example, it was unclear in the RUC recommendations as to what tasks are involved when clinical staff engage with the patient throughout the month to perform education about the device and re-education protocols after the initial enrollment.

The CPT Editorial Panel is deleting CPT code 93299 for CY 2020. We note this differs from the RUC recommendations for this code from the October 2018 meeting, which stated that the specialty society intended to submit a coding proposal to the CPT Editorial Panel to delete CPT code 93299, as it would no longer be necessary to have a separate code for PE, if CPT codes 93297 and 93298 are allocated direct PE for CY 2020. Given that we are proposing to not allocate direct PE inputs for CPT code 93297 and 93298 for CY 2020 and CPT code 93299 is being deleted for CY 2020, we are proposing to create a G-code to describe the services previously furnished under CPT code 93299. We are proposing to create HCPCS code GTTT1 (*Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results*), to describe the services previously furnished under CPT code 93299, effective for CY 2020.

(60) Duplex Scan Arterial Inflow-Venous Outflow (CPT Codes 93X00 and 93X01)

In September 2018, the CPT Editorial Panel recommended replacing one HCPCS code (G0365) with two new codes to describe the duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access for complete bilateral and unilateral study. We are proposing the RUC-recommended work RVU of 0.80 for CPT code 93X00 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study*), as well as the RUC-recommended work RVU of 0.50 for CPT code 93X01 (*Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study*).

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Prepare room, equipment and supplies'' (CA013) activity from 4 minutes to 2 minutes for both codes in the family. Two minutes is the standard time for this clinical labor activity, and 2 minutes is also the time assigned for this activity in the reference code, CPT code 93990 (*Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)*). There was no rationale provided in the recommended materials indicating why this additional clinical labor time would be typical for the procedures, and therefore, we are proposing to refine to the standard time of 2 minutes. We are also proposing to adjust the equipment times to conform to this change in the clinical labor time.

(61) Myocardial Strain Imaging (CPT Code 933X0)

The CPT Editorial Panel deleted one Category III code and created one new Category I add-on code CPT code 933X0 to describe the work of myocardial strain imaging performed in supplement to transthoracic echocardiography services. We are proposing the RUC-recommended work RVU of 0.24.

We are proposing the RUC-recommended direct PE inputs for CPT code 933X0. However, we note that no rationale was given for the RUC-recommended 12 minutes of clinical labor time for the activity CA021

''Perform procedure/service,'' and we are requesting comment on the appropriateness of this allocated time value.

(62) Lung Function Test (CPT Code 94200)

The RUC recommended this service for survey because it appeared on a list of CMS/Other codes with Medicare utilization of 30,000 or more. According to the RUC, this service is typically reported with an E/M service and another pulmonary function test, and the RUC-recommended times would appropriately account for any overlap with other services. The RUC stated that the intraservice time involves reading and interpreting the test to determine if a significant interval change has occurred and then generating a report, which supports the 5 minutes of physician work indicated in the survey. The RUC did not agree with the specialty society that communication of the report required an additional 2 minutes of physician time over the postservice time included in the other services reported on the same day. The RUC reduced the postservice time from 2 minutes to 1 minute because the service requires minimal time to enter the results into the medical record and communicate the results to the patient and the referring physician. Based in part on these reductions in physician time, the RUC recommended a reduction in work RVU from the current value with a crosswalk to CPT code 95905 (Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report).

For CPT code 94200 (*Maximum breathing capacity, maximal voluntary ventilation*), we are proposing the RUC-recommended work RVU of 0.05. A stakeholder stated that the RUC's recommended work RVU understates the costs inherent in performing this service, and that the survey 25th percentile value of 0.10 is more accurate for this service. While we are proposing the RUC-recommended 0.05, we are soliciting public comment on this stakeholder-recommended potential alternative value.

We are proposing the RUC-recommended direct PE inputs for CPT code 94200 without refinement.

(63) Long-Term EEG Monitoring (CPT Codes 95X01, 95X02, 95X03, 95X04, 95X05, 95X06, 95X07, 95X08, 95X09, 95X10, 95X11, 95X12, 95X13, 95X14, 95X15, 95X16, 95X17, 95X18, 95X19, 95X20, 95X21, 95X22, and 95X23)

In January 2017, the RUC identified CPT code 95951 via the high volume growth screen, which considers if the service has total Medicare utilization of 10,000 or more and if utilization has increased by at least 100 percent from 2009 through 2014. The RUC recommended that this service be referred to the CPT Editorial Panel for needed changes, including code deletions, revision of code descriptors, and the addition of new codes to this family. In May 2018, the CPT Editorial Panel approved the revision of one code, deletion of five codes, and addition of 23 new codes for reporting long-term EEG professional and technical services.

We are proposing the RUC-recommended work RVU for six of the professional component codes in this family. We are proposing a work RVU of 3.86 for CPT code 95X18 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video*), a work RVU of 4.70 for CPT code 95X19 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video*), a work RVU of 4.75 for CPT code 95X20 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video*), a work RVU of 6.00 for CPT code 95X21 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video*), a work RVU of 5.40 for CPT code 95X22 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 84 hours of EEG recording, without video*) and a work RVU of 7.58 for CPT code 95X23 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, complete study; greater than 84 hours of EEG recording, with video*).

We are also proposing the RUC-recommended work RVU of 0.00 for the 13 technical component codes in the family: CPT code 95X01 (*Electroencephalogram (EEG) continuous recording, with video when performed, set-up, patient education, and take down when performed, administered in-person by EEG technologist, minimum of 8 channels*), CPT code 95X02 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; unmonitored*), CPT code 95X03 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; with intermittent monitoring and maintenance*), CPT code 95X04 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, 2–12 hours; with continuous, real-time monitoring and maintenance*), CPT code 95X05 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; unmonitored*), CPT code 95X06 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; with intermittent monitoring and maintenance*), CPT code 95X07 (*Electroencephalogram (EEG) without video, review of data, technical description by EEG technologist, each increment of 12–26 hours; with continuous, real-time monitoring and maintenance*), CPT code 95X08 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; unmonitored*), CPT code 95X09 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; with intermittent monitoring and maintenance*), CPT code 95X10 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2–12 hours; with continuous, real-time monitoring and maintenance*), CPT code 95X11 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; unmonitored*), CPT code 95X12 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; with intermittent monitoring and*

maintenance), and CPT code 95X13 (*Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12–26 hours; with continuous, real-time monitoring and maintenance*).

We disagree with the RUC-recommended work RVU of 2.00 for CPT code 95X14 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, 2–12 hours of EEG recording; without video*) and we are proposing a work RVU of 1.85 based on a crosswalk to CPT code 93314 (*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only*). CPT code 93314 is a recently-reviewed code with 2 additional minutes of intraservice time and 4 additional minutes of total time as compared to CPT code 95X14. When considering the work RVU for CPT code 95X14, we looked to the second reference code chosen by the survey participants, CPT code 95957 (*Digital analysis of electroencephalogram (EEG) (e.g., for epileptic spike analysis)*). This code has 2 additional minutes of intraservice time and 9 additional minutes of total time as compared to CPT code 95X14, yet has a work RVU of 1.98, lower than the recommended work RVU of 2.00. These time values suggested that CPT code 95X14 would be more accurately valued at a work RVU slightly below the 1.98 of CPT code 95957. We also looked at the intraservice time ratio between CPT code 95X14 and some of its predecessor codes. The intraservice time ratio with CPT code 95953 (*Monitoring for localization of cerebral seizure focus by computerized portable 16 or more channel EEG, electroencephalographic (EEG) recording and interpretation, each 24 hours, unattended*) suggests a similar potential work RVU of 1.91 (28 minutes divided by 45 minutes times a work RVU of 3.08). Based on this information, we are proposing a work RVU of 1.85 for CPT code 95X14 based on the aforementioned crosswalk to CPT code 93314.

We disagree with the RUC-recommended work RVU of 2.50 for CPT code 95X15 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, 2–12 hours of EEG recording; with video (VEEG)*) and we are proposing a work RVU of 2.35. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 95X14 and 95X15 is equivalent to the recommended interval of 0.50 RVUs. Therefore, we are proposing a work RVU of 2.35 for CPT code 95X15, based on the recommended interval of 0.50 additional RVUs above our proposed work RVU of 1.85 for CPT code 95X14. We are supporting this work RVU with a reference to CPT code 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of the 3 key components*), which shares the same intraservice time of 35 minutes and the identical work RVU of 2.35. CPT code 99310 is a lower intensity procedure but has increased total work time as compared to CPT code 95X15.

We disagree with the RUC-recommended work RVU of 3.00 for CPT code 95X16 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video*) and we are proposing a work RVU of 2.60 based on a crosswalk to CPT code 99219 (*Initial observation care, per day, for the evaluation and management of a patient, which requires 3 key components*). CPT code 99219 shares the same intraservice time of 40 minutes and has a slightly higher total time as compared to CPT code 95X16. We also note that the observation care described by CPT code 99219 shares some clinical similarities to the long term EEG monitoring described by CPT code 95X16, although we note as always that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another, and that codes do not need to share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

In addition, we believe that the proposed crosswalk to CPT code 99219 at a work RVU of 2.60 more accurately captures the intensity of CPT code 95X16. At the recommended work RVU of 3.00, the intensity of CPT code 95X16 is anomalously high in comparison to the rest of the family, higher than any of the other professional component codes. We have no reason to believe that the 24-hour EEG monitoring done without video as described in CPT code 95X16 would be notably more intense than the other codes in the same family. Furthermore, the recommendations for this code family specifically state that the codes that describe video EEG monitoring are more intense than the codes that describe non-video EEG monitoring. However, at the recommended work RVU for CPT code 95X16, this non-video form of EEG monitoring had the highest intensity in the family. At our proposed work RVU of 2.60, the intensity of CPT code 95X16 is no longer anomalously high in comparison to the rest of the family, and also remains lower than the intensity of the 24 hour EEG monitoring with video procedure described by CPT code 95X17.

We disagree with the RUC-recommended work RVU of 3.86 for CPT code 95X17 (*Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)*) and we are proposing a work RVU of 3.50 based on the survey 25th percentile value. The RUC-recommended work RVU of 3.86 was based on a crosswalk to CPT code 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires 3 key components*), a code that shares the same intraservice time of 55 minutes but has 15 additional minutes of total time as compared to CPT code 95X17, at 90 minutes as compared to 75 minutes. We disagree with the use of this crosswalk, as the 15 minutes of additional total time in CPT code 99223 result in a higher work valuation that overstates the work RVU of CPT code 95X17. These 15 additional minutes of preservice and postservice work time in the recommended crosswalk code have a calculated work RVU of 0.34 under the building block methodology; subtracting out this work RVU of 0.34 from the crosswalk code's work RVU of 3.86 results in an estimated work RVU of 3.52, which is nearly identical to the survey 25th percentile work RVU of 3.50. Similarly, if we were to calculate a total time ratio between CPT code 95X17 and the recommended crosswalk code 99223, it would produce a noticeably lower work RVU of 3.22 (75 minutes divided by 90 minutes times a work RVU of 3.86). Based on this rationale, we do not believe that it would serve the interests of relativity to propose a work RVU of 3.86 based on the recommended crosswalk.

Instead, we are proposing a work RVU of 3.50 for CPT code 95X17 based on the

survey 25th percentile value. We note that among the predecessor codes for this family, CPT code 95956 (*Monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, electroencephalographic (EEG) recording and interpretation, each 24 hours, attended by a technologist or nurse*) has a higher intraservice time of 60 minutes and a higher total time of 105 minutes at a work RVU of 3.61. This prior valuation of CPT code 95956 does not support the RUC-recommended work RVU of 3.86 for CPT code 95X17, but does support the proposed work RVU of 3.50 at the slightly lower newly surveyed work times. We also note that at the recommended work RVU of 3.86, the intensity of CPT code 95X17 was anomalously high in comparison to the rest of the family, the second-highest intensity as compared to the other professional component codes. We have no reason to believe that the 24 hour EEG monitoring done with video as described in CPT code 95X17 would be notably more intense than the other codes in the same family. At our proposed work RVU of 3.50, the intensity of CPT code 95X17 is no longer anomalously high in comparison to the rest of the family, while still remaining slightly higher than the intensity of the 24 hour EEG monitoring performed without video procedure described by CPT code 95X16.

For the direct PE inputs, we are proposing to make a series of refinements to the clinical labor times of CPT code 95X01. Many of the clinical labor times for this CPT code were derived using a survey process and were recommended to CMS at the survey median values. This was in contrast to the typical process for recommended direct PE inputs, where the inputs are usually based on either standard times or carried over from reference codes. We believe that when surveys are used to recommended direct PE inputs, we must apply a similar process of scrutiny to that used in assessing the work RVUs that are recommended based on a survey methodology. We have long expressed our concerns over the validity of the survey results used to produce work RVU recommendations, such as in the CY 2011 PFS final rule (75 FR 73328), and we have noted that over the past decade the AMA RUC has increasingly chosen to recommend the survey 25th percentile work RVU over the survey median value, potentially responding to the same concerns that we have identified.

As a result, we believe that when assessing the survey of direct PE inputs used to produce many of the recommendations for CPT code 95X01, it would be more accurate to propose the survey 25th percentile direct PE inputs as opposed to the recommended survey median direct PE inputs. Therefore, we are proposing to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from 13 minutes to 7 minutes and to refine the clinical labor time for the ''Review home care instructions, coordinate visits/prescriptions'' (CA035) activity from 10 minutes to 7 minutes. In both of these cases, the recommended clinical labor times based on the survey median values are more than double the standard time for these activities. Although we agree that additional clinical labor time would be required to carry out these activities for CPT code 95X01, we do not believe that the survey median times would be typical. We are proposing the survey 25th percentile times of 7 minutes for each activity as we believe that this time would be more typical for obtaining consent and reviewing home care instructions.

We are also proposing to refine the clinical labor time for the ''Complete pre-procedure phone calls and prescription'' (CA005) activity from 10 minutes to 3 minutes for CPT code 95X01. This is another situation where we are proposing the survey 25th percentile clinical labor time of 3 minutes instead of the survey median clinical labor time of 10 minutes. However, we also note that many of the tasks that fell under the CA005 activity code as described in the PE recommendations appear to constitute forms of indirect PE, such as collecting supplies for setup and loading equipment and supplies into vehicles. Collecting supplies and loading equipment are administrative tasks that are not individually allocable to a particular patient for a particular service, and therefore, constitute indirect PE under our methodology. Due to the fact that many of the tasks described under the CA005 activity code are forms of indirect PE, we believe that the RUC-recommended survey median clinical labor time of 10 minutes overstates the amount of direct clinical labor taking place. We believe that it is more accurate to propose the survey 25th percentile clinical labor time of 3 minutes for this activity code to reflect the non-administrative tasks performed by the clinical staff.

We are also proposing to refine the quantity of the non-sterile gloves (SB022) supply from 3 to 2 for CPT code 95X01. We note that the current reference code, CPT code 95953, uses 2 of these pairs of gloves and the survey also stated that 2 pairs of gloves were typical for the procedure. Although the recommended materials state that a pair of gloves is needed to set up the equipment, to take down the equipment, and a third is required for electrode changes, we do not agree that the use of a third pair of gloves would be typical given their usage in the reference code and in the responses from the survey.

We note that we are not proposing to refine many of the other clinical labor times for CPT code 95X01, which remain at the survey median clinical labor times. Due to the nature of the continuous recording EEG service taking place, we agree that the survey median clinical labor times of 12 minutes for the ''Prepare room, equipment and supplies'' (CA013) activity, 45 minutes for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity, and 22 minutes for the ''Clean room/equipment by clinical staff'' (CA024) activity would be typical for this procedure. We reiterate that we assess the direct PE inputs for each procedure individually based on our methodology of what would be reasonable and medically necessary for the typical patient.

For CPT codes 95X02–95X13, we are proposing to refine the clinical labor time for the ''Coordinate post-procedure services'' (CA038) activity from either 11 minutes to 5 minutes or from 22 minutes to 10 minutes as appropriate for the CPT code in question. The recommended materials for these procedures state that the tasks taking place constitute ''Merge EEG and Video files (partially automated program), confirm transfer of data, delete from laptop/computer if necessary''. We believe that many of the tasks detailed here are administrative in nature, consisting of forms of data entry, and therefore, would be considered types of indirect PE. We note that when CPT code 95812 (Electroencephalogram (EEG) extended monitoring; 41–60 minutes) was recently reviewed for CY 2017, we finalized the recommended clinical labor time of 2 minutes for ''Transfer data to reading station & archive data'', a task which we believe to be highly similar. Due to the longer duration of the procedures in CPT codes 95X02–95X13, we are proposing clinical labor times of 5 minutes and 10 minutes for the CA038 activity for these CPT codes. We are also refining the equipment time for the Technologist PACS workstation (ED050) to match the clinical labor time proposed for the CA038 activity.

For the four continuous monitoring procedures, CPT codes 95X04, 95X07, 95X10, and 95X13, we are proposing to refine the equipment time for the

ambulatory EEG review station (EQ016) equipment. The recommended equipment time for the ambulatory EEG review station was equal to four times the ''Perform procedure/service'' (CA021) clinical labor time plus a small amount of extra prep time. We do not agree that it would be typical to assign this much equipment time, as it is our understanding that one ambulatory EEG review station can be hooked up to as many as four monitors at a time for continuous monitoring. Therefore, we do not believe that each monitor would require its own review station, and that the equipment time should not be equal to four times the clinical labor of the ''Perform procedure/service'' (CA021) activity. As a result, we are proposing to refine the ambulatory EEG review station equipment time from 510 minutes to 150 minutes for CPT code 95X04, from 1,480 minutes to 400 minutes for CPT code 95X07, from 514 minutes to 154 minutes for CPT code 95X10, and from 1,495 minutes to 415 minutes for CPT code 95X13.

For the 10 professional component procedures, CPT codes 95X14–95X23, we are again proposing to refine the equipment time for the ambulatory EEG review station (EQ016) equipment. We believe that the use of the ambulatory EEG review station is analogous in these procedures to the use of the professional PACS workstation (ED053) in other procedures, and we are proposing to refine the equipment times for these 10 procedures to match our standard equipment time formula for the professional PACS workstation. Therefore, we are proposing an equipment time for the ambulatory EEG review station equal to half the preservice work time (rounded up) plus the intraservice work time for CPT codes 95X14 through 95X23. We believe that this equipment time is more accurate than the recommended equipment time, which was equal to the total work time of the procedures, as the work descriptors for CPT codes 95X14–95X23 make no mention of the ambulatory EEG review station in the postservice work period.

Finally, we are proposing to price the new ''EEG, digital, prolonged testing system with remote video, for patient home use'' (EQ394) equipment at $26,410.95 based on an invoice submission. We did not use a second invoice submitted for the new equipment for pricing, as it contained a disaggregated list of equipment components and it was not clear if they represented the same equipment item as the first invoice.

(64) Health and Behavioral Assessment and Intervention (CPT Codes 961X0, 961X1, 961X2, 961X3, 961X4, 961X5, 961X6, 961X7, and 961X8)

The 2001 Health and Behavior Assessment and Intervention (HBAI) RUC valuations were based on the old CPT code 90801 (*Psychiatric diagnostic interview evaluation*), a 60-minute service. The RUC originally recommended the Health and Behavior Assessment and Intervention procedures to be 15-minute services, approximately equal to one-quarter of the value of CPT code 90801, which we finalized without refinements. While the RUC may have assumed that these services would typically be reported in four, 15-minute services per single patient encounter, in actual claims data, there is wide variation in the number of services provided and submitted. The RUC reconsidered their rationale for the original RUC-recommended valuation of this family of codes in September 2018. The CPT Editorial Panel deleted the six existing Health and Behavior Assessment and Intervention procedure CPT codes and replaced them with nine new CPT codes.

The six deleted CPT codes include CPT code 96150 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment*), CPT code 96151 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment*), CPT code 96152 (*Health and behavior intervention, each 15 minutes, face-to-face; individual*), CPT code 96153 (*Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)*), CPT code 96154 (*Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)*), and CPT code 96155 (*Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)*).

The nine replacement HBAI CPT codes include CPT code 961X0 (*Health behavior assessment, including re-assessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)*), CPT code 961X1 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*), CPT code 961X2 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 961X3 (*Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes*), CPT code 961X4 (*Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 961X5 (*Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes*), CPT code 961X6 (*Health behavior intervention, family (with the patient present), face-to-face each additional 15 minutes (list separately in addition to code for primary service)*), CPT code 961X7 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*), CPT code 961X8 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*).

We are proposing the RUC-recommended work RVUs for each of the codes in this family as follows.

- For CPT code 961X0, we are proposing a work RVU of 2.10.
- For CPT code 961X1, we are proposing a work RVU of 1.45.
- For CPT code 961X2, we are proposing a work RVU of 0.50.
- For CPT code 961X3, we are proposing a work RVU of 0.21.
- For CPT code 961X4, we are proposing a work RVU of 0.10.
- For CPT code 961X5, we are proposing a work RVU of 1.55.
- For CPT code 961X6, we are proposing a work RVU of 0.55.
- For CPT code 961X7, we are proposing a work RVU of 1.50 (but this code will be non-covered by Medicare).
- For CPT code 961X8, we are proposing a work RVU of 0.54 (but this code will be non-covered by Medicare).

We are proposing the RUC-recommended direct PE inputs for all of the CPT codes in this family without refinement.

(66) Cognitive Function Intervention (CPT Codes 971XX and 9XXX0)

In 2017, we received HCPAC recommendations for new CPT code 97127 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, 1*) that described the services under CPT code 97532 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, each 15 minutes*). CPT code 97532 was scheduled to be deleted and replaced by the new untimed code CPT code 97127. In the CY 2018 PFS final rule (82 FR 53074 through 53076); however, we

suggested that CPT code 97127 as an untimed/per day code did not appropriately account for the variable amounts of time spent with a patient depending upon the discipline and/or setting and assigned the code a procedure status of ''I'' (Invalid). In place of CPT code 97127, we established a new HCPCS G-code, G0515 (*Development of cognitive skills to improve attention, memory, problem solving, direct patient contact, each 15 minutes*), with a work RVU of 0.44. HCPCS code G0515 maintained the descriptor and values from the former CPT code 97532.

In September 2018, the CPT Editorial Panel revised CPT code 971XX (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing and sequencing tasks), direct (one-to-one) patient contact; initial 15 minutes*) and created an add-on code, CPT code 9XXX0 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing and sequencing tasks), direct (one-to-one) patient contact; each additional 15 minutes (list separately in addition to code for primary procedure)*).

We are proposing the RUC-recommended work RVUs of 0.50 for CPT code 971XX and 0.48 for CPT code 9XXX0. We are proposing the RUC-recommended direct PE inputs for all codes in the family. We are also proposing to designate CPT codes 971XX and 9XXX0 as sometime therapy codes because the services might be appropriately furnished by therapists under the outpatient therapy services benefit (includes physical therapy, occupational therapy, or speech-language pathology) or outside the therapy benefit by physicians, NPPs, and psychologists.

(67) Open Wound Debridement (CPT Codes 97597 and 97598)

CPT code 97598 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof*) was identified by the RUC on a list of services that were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along CPT code 97597 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*) at the October 2018 RUC meeting.

We disagree with the RUC-recommended work RVU of 0.88 for CPT code 97597 and we are proposing a work RVU of 0.77 based on a crosswalk to CPT code 27369 (*Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography*). CPT code 27369 is a recently-reviewed code with the same intraservice time of 15 minutes and a total time of 28 minutes, one minute fewer than CPT code 97597. In reviewing this code, we noted that the recommended intraservice time is increasing from 14 minutes to 15 minutes (7 percent), and the recommended total time is increasing from 24 minutes to 29 minutes (21 percent); however, the RUC-recommended work RVU is increasing from 0.51 to 0.88, which is an increase of 73 percent. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear increase in the valuation of work RVUs, we believe that since the two components of work are time and intensity, modest increases in time should be appropriately reflected with a commensurate increase the work RVUs. In the case of CPT code 97597, we believed that it is more accurate to propose a work RVU of 0.77 based on a crosswalk to CPT code 27369 to account for these modest increases in the surveyed work time. We also note that even at the proposed work RVU of 0.77 the intensity of this procedure as measured by IWPUT is increasing by more than 50 percent over the current value.

We are proposing the RUC-recommended work RVU of 0.50 for CPT code 97598. We are also proposing the RUC-recommended direct PE inputs for all codes in the family.

(68) Negative Pressure Wound Therapy (CPT Codes 97607 and 97608)

In the CY 2013 final rule with comment period, we created two HCPCS codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries using equipment that is not paid for as durable medical equipment: G0456 (*Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters*) and G0457 (*Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm*). For CY 2015, the CPT Editorial Panel created CPT codes 97607 (Negative *pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate*) and 97608 (Negative pressure wound therapy, (*e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate*) to describe negative pressure wound therapy with the use of a disposable system. In addition, CPT codes 97605 (*Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters*) and 97606 (*Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters*) were revised to specify the use of durable medical equipment. Based upon the revised coding scheme for negative pressure wound therapy, we deleted the G-codes. Due to concerns that we had with these services, we contractor priced CPT codes 97607 and 97608 beginning in CY 2015 (79 FR 67670). In the CY 2016 Final Rule (80 FR 71005),

in response to comment expressing disappointment with CMS' decision to contractor price these codes, we noted that there were obstacles to developing accurate payment rates for these services within the PE RVU methodology, including the indirect PE allocation for the typical practitioners who furnish these services and the diversity of the products used in furnishing these services.

We have received repeated requests from stakeholders, including in comment received in response to the CY 2019 PFS final rule, to assign an active status to these codes, meaning we would assign rates to the codes rather than allowing them to be contractor priced. In that rule, (83 FR 59473), we noted that we received a request that CMS should assign direct cost inputs and PE RVUs to CPT codes 97607 and 97608, and we indicated that we would take this feedback from commenters under consideration for future rulemaking.

In response to stakeholder feedback, we evaluated the codes and determined there was adequate volume to assign an active status. We are proposing to assign an active status to CPT codes 97607 and 97608 and we are proposing the work RVUs as recommended by the RUC that we received for CY 2015 when the CPT Editorial Panel created these codes. Thus, we are proposing a work RVU of 0.41 for CPT code 97607 and a work RVU of 0.46 for CPT code 97608. Similarly, we are proposing the RUC-recommended direct PE inputs originally for CY 2015 with the following refinement: For the clinical labor activity ''check dressings & wound/home care instructions/coordinate office visits/prescriptions,'' we are refining the clinical labor time to the standard 2 minutes for this task. In addition, the direct inputs for these codes include the new supply item, ''kit, negative pressure wound therapy, disposable.'' A search of publicly available commercial pricing data indicates that a unit price of approximately $100 is appropriate, and therefore, we are proposing this price for this supply item. If more accurate invoices are available, we are soliciting such invoices to more accurately price it.

(69) Ultrasonic Wound Assessment (CPT Code 97610)

In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the Committee. CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*) was flagged for CPT 2015 and reviewed at the October 2018 RAW meeting. The Workgroup indicated that the utilization is continuing to increase for this service, and recommended that it be resurveyed for physician work and practice expense for the January 2019 RUC meeting.

We are proposing the RUC-recommend work 0.40 for CPT code 97610. We are also proposing the RUC-recommended direct PE inputs for CPT code 97610.

(70) Online Digital Evaluation Service (e-Visit) (CPT Codes 98X00, 98X01, and 98X02)

In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to-face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The HCPAC reviewed and made recommendations for CPT code 98X00 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), CPT code 98X01 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and CPT code 98X02 (*Qualified nonphysician qualified healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). CPT codes 9X0X1–9X0X3 are for practitioners who can independently bill E/M services while CPT codes 98X00–98X02 are for practitioners who cannot independently bill E/M services.

The statutory requirements that govern the Medicare benefit are specific regarding which practitioners may bill for E/M services. As such, when codes are established that describe E/M services that fall outside the Medicare benefit category of the practitioners who may bill for that service, we have typically created parallel HCPCS G-codes with descriptors that refer to the performance of an ''assessment'' rather than an ''evaluation''. We acknowledge that there are qualified non-physician health care professionals who will likely perform these services. Therefore, for CY 2020, we are proposing separate payment for online digital assessments via three HCPCS G-codes that mirror the RUC recommendations for CPT codes 98X00–98X02. The proposed HCPCS G codes and descriptors are as follows:

- HCPCS code GNPP1 (*Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*);
- HCPCS code GNPP2 (*Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*); and
- HCPCS code GNPP3 (*Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*).

For CY 2020, we are proposing a work RVU of 0.25 for CPT code GNPP1, which reflects the RUC-recommended work RVU for CPT code 98X00. For HCPCS codes GNPP2 and GNPP3, we believe that the 25th percentile work RVU associated with CPT codes 98X01 and 98X02 respectively, better reflects the intensity of performing these services, as well as the methodology used to value the other codes in the family, all of which use the 25th percentile work RVU. Therefore, we are proposing a work RVU of 0.44 for HCPCS code GNPP1 and a work RVU of 0.69 for HCPCS code GNPP2.

We are proposing the direct PE inputs associated with CPT codes 98X00, 98X01, and 98X02 for GNPP1, GNPP2, and GNPP3 respectively.

(71) Emergency Department Visits (CPT Codes 99281, 99282, 99283, 99284, and 99285)

In the CY 2018 PFS final rule, we finalized a proposal to nominate CPT codes 99281–99285 as potentially misvalued based on information suggesting that the work RVUs for emergency department visits may not appropriately reflect the full resources involved in furnishing these services (FR 82 53018.) These five codes were surveyed and reviewed for the April 2018 RUC meeting. For CY 2020 we are proposing the RUC-recommended work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285.

The RUC did not recommend and we are not proposing any direct PE inputs for the codes in this family.

(72) Self-Measured Blood Pressure Monitoring (CPT Codes 99X01, 99X02, 93784, 93786, 93788, and 93790)

In September 2018, the CPT Editorial Panel created two new codes and revised four other codes to describe self-measured blood pressure monitoring services and to differentiate self-measured blood pressuring monitoring services from ambulatory blood pressure monitoring services. The first of the two new codes that describe self-measured blood pressure monitoring is CPT code 99X01 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*) and is a PE only code. The second code is 99X02 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings, one minute apart, twice daily over a 30-day period* (*minimum of 12 readings*), *collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*).

The remaining four codes, which monitor ambulatory blood pressure, include CPT code 93784 (*Ambulatory blood pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report*), CPT code 93786 (*Ambulatory blood pressure monitoring, recording only*), CPT code 93788 (*Ambulatory blood pressure monitoring, scanning analysis with report*), and CPT code 93790 (*Ambulatory blood pressure monitoring, review with interpretation and report*). CPT code 93784 is a composite code that is the sum of CPT codes 93786, 93788, and 93790. CPT codes 93786 and 93788 are PE only codes.

We are proposing the RUC-recommended work RVU of 0.18 for CPT code 99X02, the RUC-recommended work RVU of 0.38 for CPT code 93784, and the RUC-recommended work RVU of 0.38 for CPT code 93790. We are proposing the RUC-recommended work RVU of 0.00 for CPT codes 93786, 93788, and 99X01. We are also proposing the RUC-recommended direct PE inputs for all codes in the family.

(73) Online Digital Evaluation Service (e-Visit) (CPT Codes 9X0X1, 9X0X2, and 9X0X3)

In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The RUC reviewed and made recommendations for CPT code 9X0X1 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*), CPT code 9X0X2 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*), and CPT code 9X0X3 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*).

For CY 2020, we are proposing the RUC-recommended work RVUs of 0.25 for CPT code 9X0X1, 0.50 for CPT code 9X0X2, and 0.80 for CPT code 9X0X3. We are proposing the RUC-recommended direct PE inputs for all codes in the family.

(74) Radiation Therapy Codes (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

For CY 2015, CPT revised the radiation therapy code set for following identification of some of the codes as potentially misvalued and the affected specialty society's contention that the provision of radiation therapy could not be accurately reported under the existing code set. In the CY 2015 PFS final rule, we finalized that we were delaying implementation of this revised code set, citing concerns with our potentially having finalized a substantial coding revision on an interim final basis. In addition, we stated that substantial work needed to be done to assure the new valuations for these codes accurately reflect the coding changes. We finalized that we would maintain inputs at CY 2014 levels by creating G-codes as necessary to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. Following the publication of the CY 2015 PFS final rule, the Patient Access and Medicare Protection Act (Pub. L. 114–115, December 28, 2015) was enacted, which included the provision that the code definitions, the work relative value units and the direct inputs for the PE RVUs for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016. In CY 2018, Congress extended this ''freeze'' in coding descriptions and inputs through CY 2019 as a provision of the Bipartisan Budget Act of 2018. For CY 2020, in the interest of payment stability, we are proposing to continue using these G-codes, as well as their current work RVUs and direct PE inputs. We are also proposing that, for CY 2020, our PE methodology will continue to include a utilization rate assumption of 60 percent for the equipment item: ER089, ''IMRT Accelerator.''

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TABLE 20: Proposed CY 2020 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
11981	Insertion, non-biodegradable drug delivery implant	1.48	1.30	1.14	No
11982	Removal, non-biodegradable drug delivery implant	1.78	1.70	1.34	No
11983	Removal with reinsertion, non-biodegradable drug delivery implant	3.30	2.10	1.91	No
15X00	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)	NEW	6.68	6.68	No
15X01	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate	NEW	6.73	6.73	No
15X02	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)	NEW	2.50	2.50	No
15X03	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate	NEW	6.83	6.83	No
15X04	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)	NEW	2.41	2.41	No
20220	Biopsy, bone, trocar, or needle; superficial (eg, ilium, sternum, spinous process, ribs)	1.27	1.93	1.65	No
20225	Biopsy, bone, trocar, or needle; deep (eg, vertebral body, femur)	1.87	3.00	2.45	No
205X1	Needle insertion(s) without injection(s); 1 or 2 muscle(s)	NEW	0.45	0.32	No
205X2	Needle insertion(s) without injection(s); 3 or more muscles	NEW	0.60	0.48	No
206X0	Manual preparation and insertion of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)	NEW	1.50	1.32	No
206X1	Manual preparation and insertion of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	NEW	2.50	1.70	No
206X2	Manual preparation and insertion of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	NEW	2.60	1.80	No
206X3	Removal of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)	NEW	1.13	1.13	No
206X4	Removal of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	NEW	1.80	1.80	No
206X5	Removal of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	NEW	2.15	2.15	No
22310	Closed treatment of vertebral body fracture(s), without manipulation, requiring and including casting or bracing	3.89	3.75	3.45	No
26020	Drainage of tendon sheath, digit and/or palm, each	5.08	7.79	6.84	No
26055	Tendon sheath incision (eg, for trigger finger)	3.11	3.75	3.11	No
26160	Excision of lesion of tendon sheath or joint capsule (eg, cyst, mucous cyst, or ganglion), hand or finger	3.57	3.57	3.57	No
27220	Closed treatment of acetabulum (hip socket) fracture(s); without manipulation	6.83	6.00	5.50	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	9.03	9.03	9.03	No
2XXX0	Excision of chest wall tumor including rib(s)	NEW		17.78	No
2XXX1	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	NEW		22.19	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
2XXX2	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	NEW		25.17	No
33020	Pericardiotomy for removal of clot or foreign body (primary procedure)	14.95	14.31	12.95	No
33025	Creation of pericardial window or partial resection for drainage	13.70	13.20	11.84	No
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	25.13	22.47	22.47	No
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	27.52	24.54	24.54	No
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	28.50	25.47	25.47	No
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	30.00	25.97	25.97	No
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)	33.12	26.59	26.59	No
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)	35.88	29.35	29.35	No
33863	Ascending aorta graft, with cardiopulmonary bypass, with aortic root replacement using valved conduit and coronary reconstruction (eg, Bentall)	58.79	59.00	58.79	No
33864	Ascending aorta graft, with cardiopulmonary bypass with valve suspension, with coronary reconstruction and valve-sparing aortic root remodeling (eg, David Procedure, Yacoub Procedure)	60.08	63.00	60.08	No
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	19.74	17.75	17.75	No
338X1	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (eg, aneurysm)	NEW	50.00	45.13	No
338X2	Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (eg, island pedicle or individual arch vessel reimplantation)	NEW	65.75	60.88	No
338XX	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection	NEW	65.00	63.40	No
34X00	Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral (List separately in addition to code for primary procedure)	NEW	9.00	9.00	No
34X01	Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s)	NEW	24.00	24.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral				
35701	Exploration not followed by surgical repair, artery; neck (eg, carotid, subclavian)	9.19	7.50	7.50	No
35X00	Exploration not followed by surgical repair, artery; upper extremity (eg, axillary, brachial, radial, ulnar)	NEW	7.12	7.12	No
35X01	Exploration not followed by surgical repair, artery; lower extremity (eg, common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)	NEW	7.50	7.50	No
37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)	1.80	1.80	1.55	No
37253	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)	1.44	1.44	1.19	No
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions	7.71	4.80	4.80	No
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions	9.66	6.00	6.00	No
3X000	Pericardiocentesis, including imaging guidance, when performed	NEW	5.00	4.40	No
3X001	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly	NEW	5.50	4.62	No
3X002	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age or any age with congenital cardiac anomaly	NEW	6.00	5.00	No
3X003	Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance	NEW	5.00	4.29	No
40808	Biopsy, vestibule of mouth	1.01	1.05	1.01	No
46945	Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group, without imaging guidance	2.21	3.69	3.69	No
46946	Hemorrhoidectomy, internal, by ligation other than rubber band; 2 or more hemorrhoid columns/groups, without imaging guidance	2.63	4.50	4.50	No
46X48	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed	NEW	5.57	5.57	No
490X1	Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration	NEW	8.35	7.55	Yes
490X2	Re-exploration of pelvic wound with removal of preperitoneal pelvic packing, including repacking, when performed	NEW	6.73	5.70	No
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	4.50	4.50	4.00	No
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	1.20	1.20	1.01	No
54640	Orchiopexy, inguinal or scrotal approach	7.73	7.73	7.73	No
62270	Spinal puncture, lumbar, diagnostic;	1.37	1.44	1.22	No
62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle	1.35	1.80	1.58	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	or catheter);				
622X0	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance	NEW	1.95	1.73	No
622X1	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	NEW	2.25	2.03	No
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill	0.48	0.48	0.48	No
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming	0.67	0.67	0.67	No
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	0.67	0.67	0.67	No
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)	0.90	0.90	0.90	No
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	1.11	1.00	0.75	No
64408	Injection(s), anesthetic agent(s) and/or steroid; vagus nerve	1.41	0.90	0.75	No
64415	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus	1.48	1.42	1.35	No
64416	Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)	1.81	1.81	1.48	No
64417	Injection(s), anesthetic agent(s) and/or steroid; axillary nerve	1.44	1.27	1.27	No
64420	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level	1.18	1.18	1.08	No
64421	Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, each additional level (List separately in addition to code for primary procedure)	1.68	0.60	0.50	No
64425	Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves	1.75	1.19	1.00	No
64430	Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve	1.46	1.15	1.00	No
64435	Injection(s), anesthetic agent(s) and/or steroid; paracervical (uterine) nerve	1.45	0.75	0.75	No
64445	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve	1.48	1.18	1.00	No
64446	Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)	1.81	1.54	1.36	No
64447	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve	1.50	1.10	1.10	No
64448	Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)	1.63	1.55	1.41	No
64449	Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)	1.81	1.55	1.27	No
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch	0.75	0.75	0.75	No
64640	#N/A	1.23	1.98	1.98	No
64XX0	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	NEW	1.52	1.52	No
64XX1	Destruction by neurolytic agent, genicular nerve branches, including imaging guidance, when performed	NEW	2.62	2.50	No
66711	Ciliary body destruction; cyclophotocoagulation, endoscopic, without concomitant removal of crystalline lens	7.93	6.36	5.62	No
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and	11.08	10.25	10.25	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation				
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)	10.43	C	C	No
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation	8.52	7.35	7.35	No
66X01	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	NEW	13.15	C	Yes
66X02	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	NEW	10.25	C	Yes
6XX00	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	NEW	1.52	1.52	No
6XX01	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)	NEW	3.39	3.39	No
70210	Radiologic examination, sinuses, paranasal, less than 3 views	0.17	0.20	0.17	No
70220	Radiologic examination, sinuses, paranasal, complete, minimum of 3 views	0.25	0.22	0.22	No
70250	Radiologic examination, skull; less than 4 views	0.24	0.20	0.18	No
70260	Radiologic examination, skull; complete, minimum of 4 views	0.34	0.29	0.28	No
70360	Radiologic examination; neck, soft tissue	0.17	0.20	0.18	No
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material	1.28	1.28	1.13	No
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)	1.38	1.13	1.06	No
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections	1.45	1.27	1.27	No
72020	Radiologic examination, spine, single view, specify level	0.15	0.16	0.16	No
72040	Radiologic examination, spine, cervical; 2 or 3 views	0.22	0.22	0.22	No
72050	Radiologic examination, spine, cervical; 4 or 5 views	0.31	0.27	0.27	No
72052	Radiologic examination, spine, cervical; 6 or more views	0.36	0.30	0.30	No
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.20	0.20	No
72072	Radiologic examination, spine; thoracic, 3 views	0.22	0.23	0.23	No
72074	Radiologic examination, spine; thoracic, minimum of 4 views	0.22	0.25	0.25	No
72080	Radiologic examination, spine; thoracolumbar junction, minimum of 2 views	0.22	0.21	0.21	No
72100	Radiologic examination, spine, lumbosacral; 2 or 3 views	0.22	0.22	0.22	No
72110	Radiologic examination, spine, lumbosacral; minimum of 4 views	0.31	0.26	0.26	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
72114	Radiologic examination, spine, lumbosacral; complete, including bending views, minimum of 6 views	0.32	0.30	0.30	No
72120	Radiologic examination, spine, lumbosacral; bending views only, 2 or 3 views	0.22	0.22	0.22	No
72125	Computed tomography, cervical spine; without contrast material	1.07	1.07	1.00	No
72126	Computed tomography, cervical spine; with contrast material	1.22	1.22	1.22	No
72127	Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72128	Computed tomography, thoracic spine; without contrast material	1.00	1.00	1.00	No
72129	Computed tomography, thoracic spine; with contrast material	1.22	1.22	1.22	No
72130	Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72131	Computed tomography, lumbar spine; without contrast material	1.00	1.00	1.00	No
72132	Computed tomography, lumbar spine; with contrast material	1.22	1.22	1.22	No
72133	Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
72170	Radiologic examination, pelvis; 1 or 2 views	0.17	0.17	0.17	No
72190	Radiologic examination, pelvis; complete, minimum of 3 views	0.21	0.25	0.25	No
72200	Radiologic examination, sacroiliac joints; less than 3 views	0.17	0.20	0.17	No
72202	Radiologic examination, sacroiliac joints; 3 or more views	0.19	0.26	0.23	No
72220	Radiologic examination, sacrum and coccyx, minimum of 2 views	0.17	0.20	0.17	No
73000	Radiologic examination; clavicle, complete	0.16	0.16	0.16	No
73010	Radiologic examination; scapula, complete	0.17	0.17	0.17	No
73020	Radiologic examination, shoulder; 1 view	0.15	0.15	0.15	No
73030	Radiologic examination, shoulder; complete, minimum of 2 views	0.18	0.18	0.18	No
73050	Radiologic examination; acromioclavicular joints, bilateral, with or without weighted distraction	0.20	0.18	0.18	No
73070	Radiologic examination, elbow; 2 views	0.15	0.16	0.16	No
73080	Radiologic examination, elbow; complete, minimum of 3 views	0.17	0.17	0.17	No
73090	Radiologic examination; forearm, 2 views	0.16	0.16	0.16	No
73650	Radiologic examination; calcaneus, minimum of 2 views	0.16	0.16	0.16	No
73660	Radiologic examination; toe(s), minimum of 2 views	0.13	0.13	0.13	No
73700	Computed tomography, lower extremity; without contrast material	1.00	1.00	1.00	No
73701	Computed tomography, lower extremity; with contrast material(s)	1.16	1.16	1.16	No
73702	Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further sections	1.22	1.22	1.22	No
74210	Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study	0.59	0.59	0.59	No
74220	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.67	0.60	0.60	No
74230	Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study	0.53	0.53	0.53	No
74240	Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.69	0.80	0.80	No
74246	Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study, including	0.69	0.90	0.90	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	glucagon, when administered				
74250	Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (eg, barium) study	0.47	0.81	0.81	No
74251	Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; double-contrast (eg, high-density barium and air via enteroclysis tube) study, including glucagon, when administered	0.69	1.17	1.17	No
74270	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	0.69	1.04	1.04	No
74280	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high density barium and air) study, including glucagon, when administered	0.99	1.26	1.26	No
74425	Urography, antegrade (pyelostogram, nephrostogram, loopogram), radiological supervision and interpretation	0.36	0.51	0.51	No
74X00	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study	NEW	0.70	0.70	No
74X01	Radiologic small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure for upper GI radiologic exam)	NEW	0.70	0.70	No
75625	Aortography, abdominal, by serialography, radiological supervision and interpretation	1.14	1.75	1.44	No
75630	Aortography, abdominal plus bilateral iliofemoral lower extremity, catheter, by serialography, radiological supervision and interpretation	1.79	2.00	2.00	No
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation	1.14	2.05	2.05	No
75774	Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation (List separately in addition to code for primary procedure)	0.36	1.01	1.01	No
76098	Radiological examination, surgical specimen	0.16	0.31	0.31	No
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation	0.20	0.20	0.20	No
76604	Ultrasound, chest (includes mediastinum), real time with image documentation	0.55	0.59	0.59	No
77073	Bone length studies (orthoroentgenogram, scanogram)	0.27	0.26	0.26	No
77074	Radiologic examination, osseous survey; limited (eg, for metastases)	0.45	0.44	0.44	No
77075	Radiologic examination, osseous survey; complete (axial and appendicular skeleton)	0.54	0.55	0.55	No
77076	Radiologic examination, osseous survey, infant	0.70	0.70	0.70	No
77077	Joint survey, single view, 2 or more joints (specify)	0.31	0.33	0.33	No
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study;	1.50	1.61	1.25	No
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)	1.50	1.56	1.00	No
78492	Myocardial imaging, positron emission tomography (PET), perfusion	1.87	1.80	1.74	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)				
78800	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (eg, head, neck, chest, pelvis), single day of imaging	0.66	0.70	0.64	No
78801	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, 2 or more areas (eg, abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days	0.79	0.79	0.73	No
78802	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, single day imaging	0.86	0.86	0.80	No
78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day of imaging	1.09	1.20	1.09	No
78804	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, requiring 2 or more days imaging	1.07	1.07	1.01	No
788X0	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day of imaging	NEW	1.60	1.49	No
788X1	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days	NEW	1.93	1.82	No
788X2	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day of imaging, or single area of imaging over 2 or more days imaging	NEW	2.23	2.12	No
788X3	Radiopharmaceutical quantification measurement(s) single area	NEW	0.51	0.47	No
78X29	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	NEW	1.76	1.40	No
78X31	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography	NEW	1.67	1.11	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	transmission scan				
78X32	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	NEW	1.90	1.84	No
78X33	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	NEW	2.07	1.71	No
78X34	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	NEW	2.26	1.90	No
78X35	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)	NEW	0.63	0.42	No
88141	Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician	0.42	0.42	0.26	No
908XX	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	NEW	0.90	0.90	No
909XX	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)	NEW	0.50	0.50	No
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report	0.17	0.10	0.10	No
92548	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report;	0.50	0.76	0.66	No
92626	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); first hour	1.40	1.40	1.40	No
92627	Evaluation of auditory function for surgically implanted device(s) candidacy or post-operative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)	0.33	0.33	0.33	No
92992	Atrial septectomy or septostomy; transvenous method, balloon (eg, Rashkind type) (includes cardiac catheterization)	C	C	C	No
92993	Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)	C	C	C	No
92X18	Ophthalmoscopy, extended; with retinal drawing and scleral depression, of peripheral retinal disease (eg, for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral	NEW	0.40	0.40	No
92X19	Ophthalmoscopy, extended; with drawing of optic nerve or macula (eg, for glaucoma, macular pathology, tumor) with interpretation and report,	NEW	0.26	0.26	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	unilateral or bilateral				
92XX0	Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)	NEW	0.96	0.86	No
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	0.52	0.52	0.52	No
933X0	Myocardial strain imaging using speckle–tracking derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)	NEW	0.24	0.24	No
93784	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; including recording, scanning analysis, interpretation and report	0.38	0.38	0.38	No
93786	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; recording only	0.00	0.00	0.00	No
93788	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; scanning analysis with report	0.00	0.00	0.00	No
93790	Ambulatory blood-pressure monitoring, utilizing report-generating software, automated, worn continuously for 24 hours or longer; review with interpretation and report	0.38	0.38	0.38	No
93X00	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	NEW	0.80	0.80	No
93X01	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	NEW	0.50	0.50	No
94200	Maximum breathing capacity, maximal voluntary ventilation	0.11	0.05	0.05	No
95X01	Electroencephalogram (EEG) continuous recording, with video when performed, setup, patient education, and takedown when performed, administered in person by EEG technologist, minimum of 8 channels	NEW	0.00	0.00	No
95X02	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; unmonitored	NEW	0.00	0.00	No
95X03	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X04	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X05	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored	NEW	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
95X06	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X07	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X08	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; unmonitored	NEW	0.00	0.00	No
95X09	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X10	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X11	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored	NEW	0.00	0.00	No
95X12	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance	NEW	0.00	0.00	No
95X13	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance	NEW	0.00	0.00	No
95X14	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; without video	NEW	2.00	1.85	No
95X15	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; with video (VEEG)	NEW	2.50	2.35	No
95X16	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video	NEW	3.00	2.60	No
95X17	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)	NEW	3.86	3.50	No
95X18	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video	NEW	3.86	3.86	No
95X19	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video (VEEG)	NEW	4.70	4.70	No
95X20	Electroencephalogram, continuous recording, physician or other qualified	NEW	4.75	4.75	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video				
95X21	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video (VEEG)	NEW	6.00	6.00	No
95X22	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, without video	NEW	5.40	5.40	No
95X23	Electroencephalogram, continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, with video (VEEG)	NEW	7.58	7.58	No
961X0	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	NEW	2.10	2.10	No
961X1	Health behavior intervention, individual, face-to-face; initial 30 minutes	NEW	1.45	1.45	No
961X2	Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.50	0.50	No
961X3	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	NEW	0.21	0.21	No
961X4	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.10	0.10	No
961X5	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	NEW	1.55	1.55	No
961X6	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.55	0.55	No
961X7	Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes	NEW	1.50	1.50	No
961X8	Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	NEW	0.54	0.54	No
971XX	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes	NEW	0.50	0.50	No
97597	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less	0.51	0.88	0.77	No
97598	Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm),	0.24	0.50	0.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)				
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	C	0.41	0.41	No
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	C	0.46	0.46	No
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	0.35	0.40	0.40	No
98X00	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	NEW	0.25	I	Yes
98X01	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	NEW	0.50	I	Yes
98X02	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	NEW	0.80	I	Yes
99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.	0.45	0.48	0.48	No
99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.	0.88	0.93	0.93	No
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.	1.34	1.42	1.42	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.	2.56	2.60	2.60	No
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.	3.80	3.80	3.80	No
99495	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of at least moderate complexity during the service period Face-to-face visit, within 14 calendar days of discharge	2.11	2.36	2.36	No
99496	Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge Medical decision making of high complexity during the service period Face-to-face visit, within 7 calendar days of discharge	3.05	3.10	3.10	No
994X0	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)	NEW	0.61	0.50	No
99X01	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	NEW	0.00	0.00	No
99X02	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	NEW	0.18	0.18	No
9X0X1	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	NEW	0.25	0.25	No
9X0X2	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	NEW	0.50	0.50	No
9X0X3	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	NEW	0.80	0.80	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
9XXX0	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)	NEW	0.48	0.48	No
G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, requiring interpretation by physician	0.42	0.42	0.26	No
G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician	0.42	0.42	0.26	No
GCCC1	Chronic care management services, first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; • chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; • comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)	NEW		0.61	No
GCCC2	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC2 for care management services of less than 20 minutes additional to the first 20 minutes of chronic care management services during a calendar month).	NEW		0.54	No
GCCC3	Complex chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, • chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, • comprehensive care plan established, implemented, revised, or monitored, • moderate or high complexity medical decision making; • 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately).	NEW		1.00	No
GCCC4	Complex chronic care management services, each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month).	NEW		0.50	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
GNPP1	Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	NEW		0.25	No
GNPP2	Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	NEW		0.44	No
GNPP3	Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	NEW		0.69	No
GPPP1	Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities	NEW		1.28	No
GPPP2	Comprehensive care management for a single high-risk disease services, e.g. Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities	NEW		0.61	No
GTTT1	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	NEW		0.00	No
GXXX1	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX2	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX3	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX4	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if	NEW		0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
	performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)				
GXXX5	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX6	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX7	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX8	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		0.00	No
GXXX9	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)	NEW		C	No
GXX10	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX11	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX12	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX13	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode (only to be billed once every 6 months).	NEW		0.00	No
GXX14	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refine-ment
GXX15	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX16	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX17	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		0.00	No
GXX18	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program); partial episode.	NEW		C	No
GXX19	Each additional 30 minutes of counseling in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW		0.00	No
GYYY1	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.	NEW		7.06	No
GYYY2	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.	NEW		6.89	No
GYYY3	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes	NEW		0.82	No
P3001	Screening papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician	0.42	0.42	0.26	Yes

TABLE 21: Proposed CY 2020 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
20225	Bone biopsy trocar/nccdlc	SC077	needle, bone biopsy	NF		0	1	S8: Supply item replaces another item; see preamble SF055	68.50
20225	Bone biopsy trocar/needle	SF055	Bone biopsy device	NF		1	0	S7: Supply item replaced by another item; see preamble SC077	-158.43
22310	Closed tx vert fx w/o manj	EF031	table, power	NF		106	108	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
26055	Incise finger tendon sheath	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
26160	Remove tendon sheath lesion	SB027	gown, staff, impervious	NF		2	1	S1: Duplicative; supply is included in SA043	-1.19
27220	Treat hip socket fracture	EF031	table, power	NF		101	103	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
33863	Ascending aortic graft	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
33864	Ascending aortic graft	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
338X1	As-aort grf f/ds oth/thn dsj	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
338X2	Transvrs a-arch grf hypthrm	L051A	RN	F	Discharge day management	0	12	L10: Aligned discharge day management clinical labor time with the discharge day management work time	6.12
35701	Expl n/flwd surg neck art	EF023	table, exam	F		36	27	E15: Refined equipment time to conform to changes in clinical	-0.06

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								labor time	
35701	Expl n/flwd surg neck art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	27	L9: Refined clinical labor to align with number of post-operative visits	-3.33
35X00	Expl n/flwd surg uxtr art	EF023	table, exam	F		36	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
35X00	Expl n/flwd surg uxtr art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	36	27	L9: Refined clinical labor to align with number of post-operative visits	-3.33
35X01	Expl n/flwd surg lxtr art	EF023	table, exam	F		63	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.24
35X01	Expl n/flwd surg lxtr art	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	63	27	L9: Refined clinical labor to align with number of post-operative visits	-13.32
35X01	Expl n/flwd surg lxtr art	SA048	pack, minimum multi-specialty visit	F		2	1	S13: Refined supply quantity to align with number of post-operative visits	-3.08
40808	Biopsy of mouth lesion	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		17	29	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.03
40808	Biopsy of mouth lesion	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	2	3	G1: See preamble text	0.37
40808	Biopsy of mouth lesion	L037D	RN/LPN/MTA	NF	Confirm order, protocol	1	0	G1: See preamble text	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					exam				
62370	Anl sp inf pmp w/mdreprg&fil	SA048	pack, minimum multi-specialty visit	NF		1	0	G8: Input removed; code is typically billed with an E/M or other evaluation service	-3.08
64400	Njx aa&/strd trigeminal nrv	EF015	mayo stand	NF		25	24	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64400	Njx aa&/strd trigeminal nrv	EF023	table, exam	NF		25	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64400	Njx aa&/strd trigeminal nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64408	Njx aa&/strd vagus nrv	EF008	chair with headrest, exam, reclining	NF		20	19	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64408	Njx aa&/strd vagus nrv	EF015	mayo stand	NF		20	19	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64408	Njx aa&/strd vagus nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64415	Njx aa&/strd brach plexus	EF015	mayo stand	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64415	Njx aa&/strd brach plexus	EF023	table, exam	NF		24	23	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64415	Njx aa&/strd brach plexus	EQ011	ECG, 3-channel (with	NF		84	83	E15: Refined equipment time to conform to changes in clinical	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			SpO2, NIBP, temp, resp)					labor time	
64415	Njx aa&/strd brach plexus	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64417	Njx aa&/strd axillary nrv	EF015	mayo stand	NF		22	21	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64417	Njx aa&/strd axillary nrv	EF023	table, exam	NF		22	21	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64417	Njx aa&/strd axillary nrv	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	81	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64417	Njx aa&/strd axillary nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64420	Njx aa&/strd ntrcost nrv 1	EF015	mayo stand	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64420	Njx aa&/strd ntrcost nrv 1	EF023	table, exam	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64420	Njx aa&/strd ntrcost nrv 1	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	88	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64420	Njx aa&/strd ntrcost nrv 1	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64425	Njx aa&/strd ii ih nerves	EF015	mayo stand	NF		30	29	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64425	Njx aa&/strd ii ih nerves	EF023	table, exam	NF		30	29	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64425	Njx aa&/strd ii ih nerves	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		90	89	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64425	Njx aa&/strd ii ih nerves	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64430	Njx aa&/strd pudendal nerve	EF023	table, exam	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64430	Njx aa&/strd pudendal nerve	EF027	table, instrument, mobile	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64430	Njx aa&/strd pudendal nerve	EQ168	light, exam	NF		28	27	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64430	Njx aa&/strd pudendal nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64435	Njx aa&/strd paracrv nrv	EF023	table, exam	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64435	Njx aa&/strd paracrv nrv	EF027	table, instrument, mobile	NF		23	22	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64435	Njx aa&/strd	EQ168	light, exam	NF		23	22	E15: Refined equipment time to	0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	paracrv nrv							conform to changes in clinical labor time	
64435	Njx aa&/strd paracrv nrv	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64445	Njx aa&/strd sciatic nerve	EF015	mayo stand	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64445	Njx aa&/strd sciatic nerve	EF023	table, exam	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64445	Njx aa&/strd sciatic nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	88	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64445	Njx aa&/strd sciatic nerve	EQ184	nerve stimulator (eg, for nerve block)	NF		29	28	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64445	Njx aa&/strd sciatic nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64447	Njx aa&/strd femoral nerve	EF015	mayo stand	NF		18	17	E15: Refined equipment time to conform to changes in clinical labor time	0.00
64447	Njx aa&/strd femoral nerve	EF023	table, exam	NF		18	17	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64447	Njx aa&/strd femoral nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		78	77	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
64447	Njx aa&/strd femoral nerve	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.37
64450	Njx aa&/strd other pn/branch	EF015	mayo stand	NF		29	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64450	Njx aa&/strd other pn/branch	EF023	table, exam	NF		29	24	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
64450	Njx aa&/strd other pn/branch	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		89	84	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	F	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	NF	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64450	Njx aa&/strd other pn/branch	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly rclatcd to physician work time	10	5	L15: Refined clinical labor time to match intraservice work time	-1.85

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					(100% of physician intra-service time)				
64640	Injection treatment of nerve	EF015	mayo stand	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64640	Injection treatment of nerve	EF031	table, power	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
64640	Injection treatment of nerve	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		64	59	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
64640	Injection treatment of nerve	EQ168	light, exam	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
64640	Injection treatment of nerve	EQ184	nerve stimulator (eg, for nerve block)	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
64640	Injection treatment of nerve	EQ214	radiofrequency generator (NEURO)	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.68
64640	Injection treatment of nerve	EQ354	radiofrequency kit for destruction by neurolytic agent	NF		44	39	E15: Refined equipment time to conform to changes in clinical labor time	-0.20
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	F	Confirm availability of prior images/stu	2	0	G1: See preamble text	-0.74

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					dies				
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	NF	Confirm availability of prior images/studies	2	0	G1: See preamble text	-0.74
64640	Injection treatment of nerve	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (100% of physician intra-service time)	25	20	L15: Refined clinical labor time to match intraservice work time	-1.85
64XX1	Dstrj nulyt agt gnclr nrv	EQ354	radiofrequency kit for destruction by neurolytic agent	NF		141	47	G1: See preamble text	-3.80
64XX1	Dstrj nulyt agt gnclr nrv	SD011	cannula (radiofrequency denervation) (SMK-C10)	NF		3	1	G1: See preamble text	-49.23
66X01	Xcapsl ctrc rmvl cplx w/ecp	EL005	lane, exam (oph)	F		180	0	G1: See preamble text	-21.01
66X01	Xcapsl ctrc rmvl cplx w/ecp	EL006	lane, screening	F		27	0	G1: See preamble text	-3.06

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			(oph)						
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Coordinate pre-surgery services (including test results)	20	0	G1: See preamble text	-7.60
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Complete pre-service diagnostic and referral forms	5	0	G1: See preamble text	-1.90
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Schedule space and equipment in facility	8	0	G1: See preamble text	-3.04
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Provide pre-service education/obtain consent	20	0	G1: See preamble text	-7.60
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Post-operative visits (total time)	207	0	G1: See preamble text	-78.66
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Discharge day management	6	0	G1: See preamble text	-2.28
66X01	Xcapsl ctrc rmvl cplx w/ecp	L038A	COMT/COT/ RN/CST	F	Complete pre-procedure phone calls and prescriptio	7	0	G1: See preamble text	-2.66

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					n				
66X01	Xcapsl ctrc rmvl cplx w/ecp	SA050	pack, ophthalmology visit (no dilation)	F		1	0	G1: See preamble text	-1.95
66X01	Xcapsl ctrc rmvl cplx w/ecp	SA082	pack, ophthalmology visit (w-dilation)	F		5	0	G1: See preamble text	-14.77
66X02	Xcapsl ctrc rmvl w/ecp	EL005	lane, exam (oph)	F		144	0	G1: See preamble text	-16.81
66X02	Xcapsl ctrc rmvl w/ecp	EL006	lane, screening (oph)	F		27	0	G1: See preamble text	-3.06
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Complete pre-procedure phone calls and prescription	7	0	G1: See preamble text	-2.66
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Schedule space and equipment in facility	8	0	G1: See preamble text	-3.04
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Post-operative visits (total time)	171	0	G1: See preamble text	-64.98
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/RN/CST	F	Discharge day management	6	0	G1: See preamble text	-2.28
66X02	Xcapsl ctrc rmvl	L038A	COMT/COT/	F	Complete	5	0	G1: See preamble text	-1.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	w/ecp		RN/CST		pre-service diagnostic and referral forms				
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/ RN/CST	F	Coordinate pre-surgery services (including test results)	20	0	G1: See preamble text	-7.60
66X02	Xcapsl ctrc rmvl w/ecp	L038A	COMT/COT/ RN/CST	F	Provide pre-service education/obtain consent	20	0	G1: See preamble text	-7.60
66X02	Xcapsl ctrc rmvl w/ecp	SA050	pack, ophthalmology visit (no dilation)	F		1	0	G1: See preamble text	-1.95
66X02	Xcapsl ctrc rmvl w/ecp	SA082	pack, ophthalmology visit (w-dilation)	F		4	0	G1: See preamble text	-11.81
6XX00	Njx aa&/strd nrv nrvtg si jt	ED050	Technologist PACS workstation	NF		36	41	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
6XX00	Njx aa&/strd nrv nrvtg si jt	SC028	needle, 18-26g 1.5-3.5in, spinal	NF		3	1	G1: See preamble text	-13.27
6XX01	Rf abltj nrv nrvtg si jt	ED050	Technologist PACS workstation	NF		51	56	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
6XX01	Rf abltj nrv nrvtg si jt	EQ354	radiofrequency kit for destruction by	NF		164	82	G1: See preamble text	-3.31

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			neurolytic agent						
6XX01	Rf abltj nrv nrvtg si jt	SD011	cannula (radiofrequency denervation) (SMK-C10)	NF		4	2	G1: See preamble text	-49.23
70210	X-ray exam of sinuses	ED050	Technologist PACS workstation	NF		13	18	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
70220	X-ray exam of sinuses	ED050	Technologist PACS workstation	NF		16	21	E18: Refined equipment time to conform to established policies for PACS Workstations	0.11
74230	X-ray xm swlng funcj c+	ED050	Technologist PACS workstation	NF		30	27	E15: Refined equipment time to conform to changes in clinical labor time	-0.07
74230	X-ray xm swlng funcj c+	EF008	chair with headrest, exam, reclining	NF		25	22	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
74230	X-ray xm swlng funcj c+	EL014	room, radiographic-fluoroscopic	NF		25	22	E15: Refined equipment time to conform to changes in clinical labor time	-5.94
74230	X-ray xm swlng funcj c+	L041B	Radiologic Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	3	2	L1: Refined time to standard for this clinical labor task	-0.41
74230	X-ray xm swlng funcj c+	L041B	Radiologic Technologist	NF	Prepare room, equipment and	4	2	L1: Refined time to standard for this clinical labor task	-0.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					supplies				
74250	X-ray exam of small bowel	EL014	room, radiographic-fluoroscopic	NF		29	26	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.94
78459	Myocrd img pet single study	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.80
78459	Myocrd img pet single study	ED050	Technologist PACS workstation	NF		73	92	E18: Refined equipment time to conform to established policies for PACS Workstations	0.42
78459	Myocrd img pet single study	EF009	chair, medical recliner	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78459	Myocrd img pet single study	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78459	Myocrd img pet single study	ER027	dose calibrator (Atomlab)	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.43
78459	Myocrd img pet single study	ER033	gamma counter, automatic	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.17
78459	Myocrd img pet single study	ER054	radiation survey meter	NF		71	86	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.05
78491	Myocrd img pet 1std rst/strs	ED020	computer workstation, nuclear	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			pharmacy management (hardware and software)						
78491	Myocrd img pet 1std rst/strs	ED050	Technologist PACS workstation	NF		73	85	E18: Refined equipment time to conform to established policies for PACS Workstations	0.26
78491	Myocrd img pet 1std rst/strs	ED053	Professional PACS Workstation	NF		17	19	E18: Refined equipment time to conform to established policies for PACS Workstations	0.12
78491	Myocrd img pet 1std rst/strs	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04
78491	Myocrd img pet 1std rst/strs	ER027	dose calibrator (Atomlab)	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78491	Myocrd img pet 1std rst/strs	ER033	gamma counter, automatic	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78491	Myocrd img pet 1std rst/strs	ER054	radiation survey meter	NF		71	79	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78492	Myocrd img pet mlt rst&strs	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42
78492	Myocrd img pet mlt rst&strs	ED050	Technologist PACS workstation	NF		103	117	E18: Refined equipment time to conform to established policies for PACS Workstations	0.31

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78492	Myocrd img pet mlt rst&strs	ED053	Professional PACS Workstation	NF		21	24	E18: Refined equipment time to conform to established policies for PACS Workstations	0.18
78492	Myocrd img pet mlt rst&strs	ER026	dosc calibration source vial set (Cs137, Co57, and Ba137)	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04
78492	Myocrd img pet mlt rst&strs	ER027	dose calibrator (Atomlab)	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78492	Myocrd img pet mlt rst&strs	ER033	gamma counter, automatic	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78492	Myocrd img pet mlt rst&strs	ER054	radiation survey meter	NF		101	109	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78800	Rp loclzj tum 1 area 1 d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		51	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78800	Rp loclzj tum 1 area 1 d img	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78800	Rp loclzj tum 1 area 1 d img	ED050	Technologist PACS workstation	NF		64	61	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
78800	Rp loclzj tum 1	EF009	chair, medical	NF		57	56	E15: Refined equipment time to	0.00

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	area 1 d img		recliner					conform to changes in clinical labor time	
78800	Rp loclzj tum 1 area 1 d img	ER016	collimator, medium energy (set of 2)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78800	Rp loclzj tum 1 area 1 d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78800	Rp loclzj tum 1 area 1 d img	ER027	dose calibrator (Atomlab)	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78800	Rp loclzj tum 1 area 1 d img	ER032	gamma camera system, single-dual head	NF		51	50	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
78800	Rp loclzj tum 1 area 1 d img	ER033	gamma counter, automatic	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78800	Rp loclzj tum 1 area 1 d img	ER053	radiation L-block tabletop shield	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78800	Rp loclzj tum 1 area 1 d img	ER054	radiation survey meter	NF		57	56	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78800	Rp loclzj tum 1 arca 1 d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and	3	2	L1: Refined time to standard for this clinical labor task	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					monitoring of patient				
78801	Rp loclzj tum 2+area 1+d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78801	Rp loclzj tum 2+area 1+d img	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78801	Rp loclzj tum 2+area 1+d img	ED050	Technologist PACS workstation	NF		75	72	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
78801	Rp loclzj tum 2+area 1+d img	EF009	chair, medical recliner	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	ER027	dose calibrator (Atomlab)	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78801	Rp loclzj tum 2+area 1+d img	ER032	gamma camera system, single-dual head	NF		58	57	E15: Refined equipment time to conform to changes in clinical labor time	-2.14

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78801	Rp loclzj tum 2+area 1+d img	ER033	gamma counter, automatic	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78801	Rp loclzj tum 2+area 1+d img	ER053	radiation L-block tabletop shield	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	ER054	radiation survey meter	NF		67	66	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78801	Rp loclzj tum 2+area 1+d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	3	2	L1: Refined time to standard for this clinical labor task	-0.62
78801	Rp loclzj tum 2+area 1+d img	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78802	Rp loclzj tum whbdy 1 d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		68	67	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78802	Rp loclzj tum whbdy 1 d img	ED020	computer workstation, nuclear pharmacy management (hardware and	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.05

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			software)						
78802	Rp loclzj tum whbdy 1 d img	ED050	Technologist PACS workstation	NF		85	82	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.07
78802	Rp loclzj tum whbdy 1 d img	EF009	chair, medical recliner	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78802	Rp loclzj tum whbdy 1 d img	ER016	collimator, medium energy (set of 2)	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78802	Rp loclzj tum whbdy 1 d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78802	Rp loclzj tum whbdy 1 d img	ER027	dose calibrator (Atomlab)	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78802	Rp loclzj tum whbdy 1 d img	ER032	gamma camera system, single-dual head	NF		68	67	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
78802	Rp loclzj tum whbdy 1 d img	ER033	gamma counter, automatic	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78802	Rp loclzj tum whbdy 1 d img	ER053	radiation L-block tabletop shield	NF		77	76	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78802	Rp loclzj tum whbdy 1 d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial	3	2	L1: Refined time to standard for this clinical labor task	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					positioning and monitoring of patient				
78803	Rp loclzj tum spect 1 area	ED019	computer workstation, nuclear medicine analysis-viewing	NF		89	86	E15: Refined equipment time to conform to changes in clinical labor time	-0.63
78803	Rp loclzj tum spect 1 area	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.16
78803	Rp loclzj tum spect 1 area	ED050	Technologist PACS workstation	NF		103	98	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.11
78803	Rp loclzj tum spect 1 area	ED053	Professional PACS Workstation	NF		30	27	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78803	Rp loclzj tum spect 1 area	EF009	chair, medical recliner	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
78803	Rp loclzj tum spect 1 area	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
78803	Rp loclzj tum spect 1 area	ER027	dose calibrator (Atomlab)	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.09

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78803	Rp loclzj tum spect 1 area	ER032	gamma camera system, single-dual head	NF		89	86	E15: Refined equipment time to conform to changes in clinical labor time	-6.42
78803	Rp loclzj tum spect 1 area	ER033	gamma counter, automatic	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.23
78803	Rp loclzj tum spect 1 area	ER053	radiation L-block tabletop shield	NF		95	92	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
78803	Rp loclzj tum spect 1 area	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	5	2	L1: Refined time to standard for this clinical labor task	-1.85
78804	Rp loclzj tum whbdy 2+d img	ED019	computer workstation, nuclear medicine analysis-viewing	NF		163	162	E15: Refined equipment time to conform to changes in clinical labor time	-0.21
78804	Rp loclzj tum whbdy 2+d img	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78804	Rp loclzj tum whbdy 2+d img	ED050	Technologist PACS	NF		185	182	E18: Refined equipment time to conform to established policies for	-0.07

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			workstation					PACS Workstations	
78804	Rp loclzj tum whbdy 2+d img	ED053	Professional PACS Workstation	NF		23	20	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
78804	Rp loclzj tum whbdy 2+d img	EF009	chair, medical recliner	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78804	Rp loclzj tum whbdy 2+d img	ER016	collimator, medium energy (set of 2)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
78804	Rp loclzj tum whbdy 2+d img	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78804	Rp loclzj tum whbdy 2+d img	ER027	dose calibrator (Atomlab)	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
78804	Rp loclzj tum whbdy 2+d img	ER032	gamma camera system, single-dual head	NF		163	162	E15: Refined equipment time to conform to changes in clinical labor time	-2.14
78804	Rp loclzj tum whbdy 2+d img	ER033	gamma counter, automatic	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	-0.08
78804	Rp loclzj tum whbdy 2+d img	ER053	radiation L-block tabletop shield	NF		172	171	E15: Refined equipment time to conform to changes in clinical labor time	0.00
78804	Rp loclzj tum whbdy 2+d img	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial	3	2	L1: Refined time to standard for this clinical labor task	-0.62

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					positioning and monitoring of patient				
78804	Rp loclzj tum whbdy 2+d img	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
788X0	Rp loclzj tum spect w/ct 1	ED019	computer workstation, nuclear medicine analysis-viewing	NF		99	96	E15: Refined equipment time to conform to changes in clinical labor time	-0.63
788X0	Rp loclzj tum spect w/ct 1	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.16
788X0	Rp loclzj tum spect w/ct 1	ED050	Technologist PACS workstation	NF		114	109	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.11
788X0	Rp loclzj tum spect w/ct 1	ED053	Professional PACS Workstation	NF		33	30	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
788X0	Rp loclzj tum spect w/ct 1	EF009	chair, medical recliner	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X0	Rp loclzj tum spect w/ct 1	ER026	dosc calibration source vial set	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			(Cs137, Co57, and Ba137)						
788X0	Rp loclzj tum spect w/ct 1	ER027	dose calibrator (Atomlab)	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.09
788X0	Rp loclzj tum spect w/ct 1	ER033	gamma counter, automatic	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.23
788X0	Rp loclzj tum spect w/ct 1	ER053	radiation L-block tabletop shield	NF		105	102	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X0	Rp loclzj tum spect w/ct 1	ER097	gamma camera system, single-dual head SPECT CT	NF		99	96	E15: Refined equipment time to conform to changes in clinical labor time	-5.28
788X0	Rp loclzj tum spect w/ct 1	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	5	2	L1: Refined time to standard for this clinical labor task	-1.85
788X1	Rp loclzj tum spect 2 areas	ED019	computer workstation, nuclear medicine analysis-viewing	NF		175	170	E15: Refined equipment time to conform to changes in clinical labor time	-1.04
788X1	Rp loclzj tum spect 2 areas	ED020	computer workstation, nuclear	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.27

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			pharmacy management (hardware and software)						
788X1	Rp loclzj tum spect 2 areas	ED050	Technologist PACS workstation	NF		194	187	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.15
788X1	Rp loclzj tum spect 2 areas	ED053	Professional PACS Workstation	NF		38	35	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
788X1	Rp loclzj tum spect 2 areas	EF009	chair, medical recliner	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X1	Rp loclzj tum spect 2 areas	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X1	Rp loclzj tum spect 2 areas	ER027	dose calibrator (Atomlab)	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
788X1	Rp loclzj tum spect 2 areas	ER032	gamma camera system, single-dual head	NF		175	170	E15: Refined equipment time to conform to changes in clinical labor time	-10.70
788X1	Rp loclzj tum spect 2 areas	ER033	gamma counter, automatic	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.39
788X1	Rp loclzj tum spect 2 areas	ER053	radiation L-block tabletop shield	NF		181	176	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X1	Rp loclzj tum spect 2 areas	L049A	Nuclear Medicine	NF	Prepare, set-up and	7	2	L1: Refined time to standard for this clinical labor task	-3.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			Technologist		start IV, initial positioning and monitoring of patient				
788X2	Rp loclzj tum spect w/ct 2	ED019	computer workstation, nuclear medicine analysis-viewing	NF		200	195	E15: Refined equipment time to conform to changes in clinical labor time	-1.04
788X2	Rp loclzj tum spect w/ct 2	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.27
788X2	Rp loclzj tum spect w/ct 2	ED050	Technologist PACS workstation	NF		227	220	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.15
788X2	Rp loclzj tum spect w/ct 2	ED053	Professional PACS Workstation	NF		43	40	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.18
788X2	Rp loclzj tum spect w/ct 2	EF009	chair, medical recliner	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X2	Rp loclzj tum spect w/ct 2	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
788X2	Rp loclzj tum	ER027	dose	NF		212	207	E15: Refined equipment time to	-0.14

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	spect w/ct 2		calibrator (Atomlab)					conform to changes in clinical labor time	
788X2	Rp loclzj tum spect w/ct 2	ER033	gamma counter, automatic	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.39
788X2	Rp loclzj tum spect w/ct 2	ER053	radiation L-block tabletop shield	NF		212	207	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
788X2	Rp loclzj tum spect w/ct 2	ER097	gamma camera system, single-dual head SPECT CT	NF		200	195	E15: Refined equipment time to conform to changes in clinical labor time	-8.80
788X2	Rp loclzj tum spect w/ct 2	L049A	Nuclear Medicine Technologist	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	7	2	L1: Refined time to standard for this clinical labor task	-3.08
788X2	Rp loclzj tum spect w/ct 2	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78X29	Myocrd img pet 1 std w/ct	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.80

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78X29	Myocrd img pet 1 std w/ct	ED050	Technologist PACS workstation	NF		83	103	E18: Refined equipment time to conform to established policies for PACS Workstations	0.44
78X29	Myocrd img pet 1 std w/ct	ED053	Professional PACS Workstation	NF		25	23	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.12
78X29	Myocrd img pet 1 std w/ct	EF009	chair, medical recliner	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78X29	Myocrd img pet 1 std w/ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78X29	Myocrd img pet 1 std w/ct	ER027	dose calibrator (Atomlab)	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.43
78X29	Myocrd img pet 1 std w/ct	ER033	gamma counter, automatic	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.17
78X29	Myocrd img pet 1 std w/ct	ER054	radiation survey meter	NF		81	96	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.05
78X31	Myocrd img pet rst/strs w/ct	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42
78X31	Myocrd img pet rst/strs w/ct	ED050	Technologist PACS workstation	NF		83	96	E18: Refined equipment time to conform to established policies for PACS Workstations	0.29
78X31	Myocrd img pet	ED053	Professional	NF		19	21	E18: Refined equipment time to	0.12

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	rst/strs w/ct		PACS Workstation					conform to established policies for PACS Workstations	
78X31	Myocrd img pet rst/strs w/ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04
78X31	Myocrd img pet rst/strs w/ct	ER027	dose calibrator (Atomlab)	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78X31	Myocrd img pet rst/strs w/ct	ER033	gamma counter, automatic	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78X31	Myocrd img pet rst/strs w/ct	ER054	radiation survey meter	NF		81	89	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78X32	Myocrd img pet rst&strs ct	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.42
78X32	Myocrd img pet rst&strs ct	ED050	Technologist PACS workstation	NF		123	137	E18: Refined equipment time to conform to established policies for PACS Workstations	0.31
78X32	Myocrd img pet rst&strs ct	ED053	Professional PACS Workstation	NF		24	25	E18: Refined equipment time to conform to established policies for PACS Workstations	0.06
78X32	Myocrd img pet rst&strs ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
78X32	Myocrd img pet rst&strs ct	ER027	dose calibrator (Atomlab)	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.23
78X32	Myocrd img pet rst&strs ct	ER033	gamma counter, automatic	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.62
78X32	Myocrd img pet rst&strs ct	ER054	radiation survey meter	NF		121	129	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.02
78X33	Myocrd img pet 2rtracer	ED019	computer workstation, nuclear medicine analysis-viewing	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.22
78X33	Myocrd img pet 2rtracer	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.96
78X33	Myocrd img pet 2rtracer	ED053	Professional PACS Workstation	NF		25	27	E18: Refined equipment time to conform to established policies for PACS Workstations	0.12
78X33	Myocrd img pet 2rtracer	EF009	chair, medical recliner	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78X33	Myocrd img pet 2rtracer	EQ007	ECG R-wave trigger (gating) device	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.46
78X33	Myocrd img pet 2rtracer	ER026	dose calibration	NF		146	164	E1: Refined equipment time to conform to established policies for	0.08

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			source vial set (Cs137, Co57, and Ba137)					non-highly technical equipment	
78X33	Myocrd img pet 2rtracer	ER027	dosc calibrator (Atomlab)	NF		146	164	E1: Rcfincd cquipmcnt timc to conform to established policies for non-highly technical equipment	0.52
78X33	Myocrd img pet 2rtracer	ER033	gamma counter, automatic	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.40
78X33	Myocrd img pet 2rtracer	ER054	radiation survey meter	NF		146	164	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78X33	Myocrd img pet 2rtracer	ER109	PET Generator Infusion Cart	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.02
78X33	Myocrd img pet 2rtracer	ER110	PET Refurbished Imaging Cardiac Configuration	NF		175	150	E2: Refined equipment time to conform to established policies for highly technical equipment	-22.37
78X33	Myocrd img pet 2rtracer	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78X34	Myocrd img pet 2rtracer ct	ED019	computer workstation, nuclear medicine analysis-viewing	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-5.22
78X34	Myocrd img pet 2rtracer ct	ED020	computer workstation, nuclear	NF		166	184	E1: Rcfincd cquipmcnt timc to conform to established policies for non-highly technical equipment	0.96

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			pharmacy management (hardware and software)						
78X34	Myocrd img pet 2rtracer ct	ED053	Professional PACS Workstation	NF		25	29	E18: Refined equipment time to conform to established policies for PACS Workstations	0.24
78X34	Myocrd img pet 2rtracer ct	EF009	chair, medical recliner	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.07
78X34	Myocrd img pet 2rtracer ct	EQ007	ECG R-wave trigger (gating) device	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.46
78X34	Myocrd img pet 2rtracer ct	ER026	dose calibration source vial set (Cs137, Co57, and Ba137)	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.08
78X34	Myocrd img pet 2rtracer ct	ER027	dose calibrator (Atomlab)	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.52
78X34	Myocrd img pet 2rtracer ct	ER033	gamma counter, automatic	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	1.40
78X34	Myocrd img pet 2rtracer ct	ER054	radiation survey meter	NF		166	184	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.06
78X34	Myocrd img pet 2rtracer ct	ER109	PET Generator Infusion Cart	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-3.02
78X34	Myocrd img pet 2rtracer ct	ER111	PET/CT Imaging Camera	NF		195	170	E2: Refined equipment time to conform to established policies for highly technical equipment	-64.85

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
			Cardiac Configuration						
78X34	Myocrd img pet 2rtracer ct	SM022	sanitizing cloth-wipe (surface, instruments, equipment)	NF		10	5	S5: Refined supply quantity to conform with other codes in the family	-0.29
78X35	Aqmbf pet rest & rx stress	ED019	computer workstation, nuclear medicine analysis-viewing	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.63
78X35	Aqmbf pet rest & rx stress	ED020	computer workstation, nuclear pharmacy management (hardware and software)	NF		20	21	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.05
78X35	Aqmbf pet rest & rx stress	EQ007	ECG R-wave trigger (gating) device	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.05
78X35	Aqmbf pet rest & rx stress	ER109	PET Generator Infusion Cart	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-0.36
78X35	Aqmbf pet rest & rx stress	ER111	PET/CT Imaging Camera Cardiac Configuration	NF		23	20	E2: Refined equipment time to conform to established policies for highly technical equipment	-7.78
88141	Cytopath c/v interpret	EP024	microscope, compound	NF		14	10	G1: See preamble text	-0.13

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
88141	Cytopath c/v interpret	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
88141	Cytopath c/v interpret	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
908XX	Bfb training 1st 15 min	EF031	table, power	NF		31	29	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
93297	Icm device interrogat remotc	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		40	0	G1: See preamble text	-18.51
93297	Icm device interrogat remote	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	40	0	G1: See preamble text	-14.80
93297	Icm device interrogat remote	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93298	Ilr device	EQ198	pacemaker	NF		76	0	G1: See preamble text	-35.17

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	interrogat remote		follow-up system (incl software and hardware) (Paceart)						
93298	Ilr device interrogat remote	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	76	0	G1: See preamble text	-28.12
93298	Ilr device interrogat remote	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93299	Icm/ilr remote tech serv	EQ198	pacemaker follow-up system (incl software and hardware) (Paceart)	NF		76	0	G1: See preamble text	-35.17
93299	Icm/ilr remote tech serv	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	76	0	G1: See preamble text	-28.12
93299	Icm/ilr remote tech serv	SK057	paper, laser printing (each sheet)	NF		10	0	G1: See preamble text	-0.13
93X00	Dup-scan hemo	ED050	Technologist	NF		101	99	E15: Refined equipment time to	-0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	compl bi std		PACS workstation					conform to changes in clinical labor time	
93X00	Dup-scan hemo compl bi std	EL016	room, ultrasound, vascular	NF		86	84	E15: Refined equipment time to conform to changes in clinical labor time	-3.57
93X00	Dup-scan hemo compl bi std	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	4	2	L1: Refined time to standard for this clinical labor task	-1.08
93X01	Dup-scan hemo compl uni std	ED050	Technologist PACS workstation	NF		60	58	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
93X01	Dup-scan hemo compl uni std	EL016	room, ultrasound, vascular	NF		47	45	E15: Refined equipment time to conform to changes in clinical labor time	-3.57
93X01	Dup-scan hemo compl uni std	L054A	Vascular Technologist	NF	Prepare room, equipment and supplies	4	2	L1: Refined time to standard for this clinical labor task	-1.08
95X01	Eeg cont rec w/vid eeg tech	L047B	REEGT	NF	Complete pre-procedure phone calls and prescription	10	3	G1: See preamble text	-3.29
95X01	Eeg cont rec w/vid eeg tech	L047B	REEGT	NF	Provide education/obtain consent	13	7	G1: See preamble text	-2.82
95X01	Eeg cont rec w/vid eeg tech	L047B	REEGT	NF	Review home care	10	7	G1: See preamble text	-1.41

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					instructions, coordinate visits/prescriptions				
95X01	Eeg cont rec w/vid eeg tech	SB022	gloves, non-sterile	NF		3	2	S6: Refined supply quantity to what is typical for the procedure	-0.19
95X02	Eeg w/o vid 2-12 hr unmntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X02	Eeg w/o vid 2-12 hr unmntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X03	Eeg wo vid 2-12hr intmt mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X03	Eeg wo vid 2-12hr intmt mntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X04	Eeg w/o vid 2-12hr cont mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X04	Eeg w/o vid 2-12hr cont mntr	EQ016	EEG review station, ambulatory	NF		510	150	G1: See preamble text	-11.34
95X04	Eeg w/o vid 2-12hr cont mntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X05	Eeg wo vid ea 12-26hr unmntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
95X05	Eeg wo vid ea 12-26hr unmntr	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X06	Eeg w/o vid ea 12-26hr intmt	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X06	Eeg w/o vid ea 12-26hr intmt	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X07	Eeg w/o vid ea 12-26hr cont	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X07	Eeg w/o vid ea 12-26hr cont	EQ016	EEG review station, ambulatory	NF		1480	400	G1: See preamble text	-34.02
95X07	Eeg w/o vid ea 12-26hr cont	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X08	Veeg 2-12 hr unmonitored	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X08	Veeg 2-12 hr unmonitored	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X09	Veeg 2-12 hr intmt mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X09	Veeg 2-12 hr intmt mntr	L047B	REEGT	NF	Coordinate post-procedure	11	5	G1: See preamble text	-2.82

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					services				
95X10	Veeg 2-12 hr cont mntr	ED050	Technologist PACS workstation	NF		22	5	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
95X10	Veeg 2-12 hr cont mntr	EQ016	EEG review station, ambulatory	NF		514	154	G1: See preamble text	-11.34
95X10	Veeg 2-12 hr cont mntr	L047B	REEGT	NF	Coordinate post-procedure services	11	5	G1: See preamble text	-2.82
95X11	Veeg ea 12-26 hr unmntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X11	Veeg ea 12-26 hr unmntr	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X12	Veeg ea 12-26hr intmt mntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X12	Veeg ea 12-26hr intmt mntr	L047B	REEGT	NF	Coordinate post-procedure services	22	10	G1: See preamble text	-5.64
95X13	Veeg ea 12-26hr cont mntr	ED050	Technologist PACS workstation	NF		44	10	E15: Refined equipment time to conform to changes in clinical labor time	-0.75
95X13	Veeg ea 12-26hr cont mntr	EQ016	EEG review station, ambulatory	NF		1495	415	G1: See preamble text	-34.02
95X13	Veeg ea 12-26hr cont mntr	L047B	REEGT	NF	Coordinate post-procedure	22	10	G1: See preamble text	-5.64

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					services				
95X14	Eeg phys/qhp 2-12 hr w/o vid	EQ016	EEG review station, ambulatory	NF		48	32	G1: See preamble text	-0.50
95X15	Eeg phys/qhp 2-12 hr w/veeg	EQ016	EEG review station, ambulatory	NF		55	40	G1: See preamble text	-0.47
95X16	Eeg phys/qhp ea incr w/o vid	EQ016	EEG review station, ambulatory	NF		60	45	G1: See preamble text	-0.47
95X17	Eeg phy/qhp ea incr w/veeg	EQ016	EEG review station, ambulatory	NF		75	60	G1: See preamble text	-0.47
95X18	Eeg phy/qhp>36<60 hr w/o vid	EQ016	EEG review station, ambulatory	NF		85	70	G1: See preamble text	-0.47
95X19	Eeg phy/qhp>36<60 hr w/veeg	EQ016	EEG review station, ambulatory	NF		100	85	G1: See preamble text	-0.47
95X20	Eeg phy/qhp>60<84 hr w/o vid	EQ016	EEG review station, ambulatory	NF		110	95	G1: See preamble text	-0.47
95X21	Eeg phy/qhp>60<84 hr w/veeg	EQ016	EEG review station, ambulatory	NF		130	115	G1: See preamble text	-0.47
95X22	Eeg phy/qhp>84 hr w/o vid	EQ016	EEG review station, ambulatory	NF		130	115	G1: See preamble text	-0.47
95X23	Eeg phy/qhp>84 hr w/veeg	EQ016	EEG review station, ambulatory	NF		160	145	G1: See preamble text	-0.47
97607	Neg press wnd tx </=50 sq cm	EF014	light, surgical	NF		23	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.02

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
97607	Neg press wnd tx </=50 sq cm	EF031	table, power	NF		23	20	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
97607	Neg press wnd tx </=50 sq cm	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	L1: Refined time to standard for this clinical labor task	-1.11
97608	Neg press wound tx >50 cm	EF014	light, surgical	NF		31	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
97608	Neg press wound tx >50 cm	EF031	table, power	NF		31	28	E15: Refined equipment time to conform to changes in clinical labor time	-0.05
97608	Neg press wound tx >50 cm	L037D	RN/LPN/MTA	NF	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	5	2	L1: Refined time to standard for this clinical labor task	-1.11
G0124	Screen c/v thin layer by md	EP024	microscope, compound	NF		14	10	G1: See preamble text	-0.13
G0124	Screen c/v thin layer by md	L033A	Lab Technician	NF	File specimen, supplies,	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for	-0.33

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					and other materials			a particular service	
G0124	Screen c/v thin layer by md	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
G0141	Scr c/v cyto,autosys and md	EP024	microscope, compound	NF		14	10	G1: See preamble text	-0.13
G0141	Scr c/v cyto,autosys and md	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
G0141	Scr c/v cyto,autosys and md	L045A	Cytotechnologist	NF	Perform regulatory mandated quality assurance activity (service period)	7	5	G1: See preamble text	-0.90
P3001	Screening pap smear by phys	EP024	microscope, compound	NF		16	10	G1: See preamble text	-0.19
P3001	Screening pap smear by phys	L033A	Lab Technician	NF	File specimen, supplies, and other materials	1	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
P3001	Screening pap	L045A	Cytotechnolog	NF	Perform	7	5	G1: See preamble text	-0.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
	smear by phys		ist		regulatory mandated quality assurance activity (service period)				

TABLE 22: Proposed CY 2020 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
52441, 52442	Urolift Implant and implantation device	SD291	$814.89	$875.00	7%	3	24,149
92546, 92548, 92XX0	CDP-computerized dynamic posturography system	EQ002	$68,842.62	$86,334.50	25%	6	80,359

TABLE 23: Proposed CY 2020 New Invoices

CPT/ HCPCS codes	Item Name	CMS code	Average price	Number of Invoices	NF Allowed Services
15X01, 15X03	Liposuction system	EQ395	$22,039.05	1	1,565
205X1, 205X2	needle, dry needling	SC107	$0.25	3	8
37765, 37766	tumescent tubing	SD333	$11.00	3	18,700
37765, 37766	tumescent pump	EQ393	$1,750.00	1	18,700
64430, 64435	pudendal block tray, sterile	SA129	$5.24	1	1,254
78459, 78491, 78492, 78X33	PET Refurbished Imaging Cardiac Configuration	ER110	$425,000.00	1	65,277
78491, 78492, 78X31, 78X32, 78X33, 78X34	IV line kit for Rb Generator	SA130	$16.98	7	130,539
78491, 78492, 78X31, 78X32, 78X33, 78X34, 78X35	PET Generator Infusion Cart	ER109	$47,052.80	5	130,585
78X29, 78X31, 78X32, 78X34, 78X35	PET/CT Imaging Camera Cardiac Configuration	ER111	$1,232,226.44	4	65,798
788X3	Software and hardware package for tumor and other distribution Quantitation	ER112	$40,535.75	4	23
95X01, 95X11, 95X12, 95X13	EEG, digital, prolonged testing system with remote video, for patients home use	EQ394	$26,410.95	2	251,218
97607, 97608	kit, negative pressure wound therapy, disposable	SA131	$100.00	0	759

TABLE 24: Proposed CY 2020 No PE Refinements

HCPCS	Description
11981	Insert drug implant device
11982	Remove drug implant device
11983	Remove/insert drug implant
15X00	grfg autol soft tiss dir exc
15X01	grfg autol fat lipo 50 cc/<
15X02	grfg autol fat lipo ea addl
15X03	grfg autol fat lipo 25 cc/<
15X04	gfrg autol fat lipo ea addl
20220	Bone biopsy trocar/needle
205X1	Ndl insj w/o njx 1 or 2 musc
205X2	Ndl insj w/o njx 3+ musc
206X0	Mnl prep&insj dp rx dlvr dev
206X1	Mnl prep&insj imed rx dev
206X2	Mnl prep&insj i-artic rx dev
206X3	Rmvl deep rx delivery device
206X4	Rmvl imed rx delivery device
206X5	Rmvl i-artic rx delivery dev
26020	Drain hand tendon sheath
27279	Arthrodesis sacroiliac joint
33020	Incision of heart sac
33025	Incision of heart sac
33361	Replace aortic valve perq
33362	Replace aortic valve open
33363	Replace aortic valve open
33364	Replace aortic valve open
33365	Replace aortic valve open
33366	Trcath replace aortic valve
33866	Aortic hemiarch graft
338XX	As-aort grf f/aortic dsj
34X00	Evasc rpr a-iliac ndgft
34X01	Evasc rpr n/a a-iliac ndgft
37252	Intrvasc us noncoronary 1st
37253	Intrvasc us noncoronary addl
37765	Stab phleb veins xtr 10-20
37766	Phleb veins - extrem 20+
3X000	Pericardiocentesis w/imaging
3X001	Prcrd drg 6yr+ w/o cgen car
3X002	Prcrd drg 0-5yr or w/anomly
3X003	Perq prcrd drg insj cath ct
46945	Int hrhc lig 1 hroid w/o img
46946	Int hrhc lig 2+hroid w/o img
46X48	Int hrhc tranal dartlzj 2+
490X1	Prpertl pel pack hemrrg trma
490X2	Reexploration pelvic wound
52441	Cystourethro w/implant
52442	Cystourethro w/addl implant

HCPCS	Description
54640	Orchiopexy ingun/scrot appr
62270	Dx lmbr spi pnxr
62272	Ther spi pnxr drg csf
622X0	Dx lmbr spi pnxr w/fluor/ct
622X1	Ther spi pnxr csf fluor/ct
62367	Analyze spine infus pump
62368	Analyze sp inf pump w/reprog
62369	Anal sp inf pmp w/reprg&fill
64421	Njx aa&/strd ntrcost nrv ea
64449	Njx aa&/strd lmbr plex nfs
64XX0	Njx aa&/strd gnclr nrv brnch
66711	Ecp ciliary body destruction
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
70210	X-ray exam of sinuses
70220	X-ray exam of sinuses
70250	X-ray exam of skull
70260	X-ray exam of skull
70360	X-ray exam of neck
70480	Ct orbit/ear/fossa w/o dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o&w/dye
72020	X-ray exam of spine 1 view
72040	X-ray exam neck spine 2-3 vw
72050	X-ray exam neck spine 4/5vws
72052	X-ray exam neck spine 6/>vws
72070	X-ray exam thorac spine 2vws
72072	X-ray exam thorac spine 3vws
72074	X-ray exam thorac spine4/>vw
72080	X-ray exam thoracolmb 2/> vw
72100	X-ray exam l-s spine 2/3 vws
72110	X-ray exam l-2 spine 4/>vws
72114	X-ray exam l-s spine bending
72120	X-ray bend only l-s spine
72125	Ct neck spine w/o dye
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72128	Ct chest spine w/o dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72131	Ct lumbar spine w/o dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72170	X-ray exam of pelvis
72190	X-ray exam of pelvis
72200	X-ray exam si joints

HCPCS	Description
72202	X-ray exam si joints 3/> vws
72220	X-ray exam sacrum tailbone
73000	X-ray exam of collar bone
73010	X-ray exam of shoulder blade
73020	X-ray exam of shoulder
73030	X-ray exam of shoulder
73050	X-ray exam of shoulders
73070	X-ray exam of elbow
73080	X-ray exam of elbow
73090	X-ray exam of forearm
73650	X-ray exam of heel
73660	X-ray exam of toe(s)
73700	Ct lower extremity w/o dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o&w/dye
74210	X-ray xm phrnx&/crv esoph c+
74220	X-ray xm esophagus 1cntrst
74240	X-ray xm upr gi trc 1cntrst
74246	X-ray xm upr gi trc 2cntrst
74251	X-ray exam of small bowel
74270	X-ray xm colon 1cntrst std
74280	X-ray xm colon 2cntrst std
74425	Contrst x-ray urinary tract
74X00	X-ray xm esophagus 2cntrst
74X01	X-ray sm int f-thru std
75625	Contrast exam abdominl aorta
75630	X-ray aorta leg arteries
75726	Artery x-rays abdomen
75774	Artery x-ray each vessel
76098	X-ray exam breast specimen
76376	3d render w/intrp postproces
76604	Us exam chest
77073	X-rays bone length studies
77074	X-rays bone survey limited
77075	X-rays bone survey complete
77076	X-rays bone survey infant
77077	Joint survey single view
788X3	Rp quan meas single area
909XX	Bfb training ea addl 15 min
92145	Corneal hysteresis deter
92548	Cdp-sot 6 cond w/i&r
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
92X18	Opscpy extnd rta draw uni/bi
92X19	Opscpy extnd on/mac draw
92XX0	Cdp-sot 6 cond w/i&r mct&adt
933X0	Myocrd strain img spckl trck
93784	Ambl bp mntr w/software
93786	Ambl bp mntr w/sw rec only
93788	Ambl bp mntr w/sw a/r
93790	Ambl bp mntr w/sw i&r
94200	Lung function test (mbc/mvv)
961X0	Hlth bhv assmt/reassessment
961X1	Hlth bhv ivntj indiv 1st 30
961X2	Hlth bhv ivntj indiv ea addl
961X3	Hlth bhv ivntj grp 1st 30
961X4	Hlth bhv ivntj grp ea addl
961X5	Hlth bhv ivntj fam 1st 30
961X6	Hlth bhv ivntj fam ea addl
961X7	Hlth bhv ivntj fam wo pt 1st
961X8	Hlth bhv ivntj fam w/o pt ea
971XX	Ther ivntj 1st 15 min
97597	Rmvl devital tis 20 cm/<
97598	Rmvl devital tis addl 20cm/<
97610	Low frequency non-thermal us
98X00	Qnhp ol dig e/m svc 5-10min
98X01	Qnhp ol dig em svc 11-20min
98X02	Qnhp ol dig e/m svc 21+ min
99281	Emergency dept visit
99282	Emergency dept visit
99283	Emergency dept visit
99284	Emergency dept visit
99285	Emergency dept visit
99495	Trans care mgmt 14 day disch
99496	Trans care mgmt 7 day disch
994X0	Rem physiol mntr ea addl 20
99X01	Self-meas bp pt educaj/train
99X02	Self-meas bp 2 readg bid 30d
9X0X1	Ol dig e/m svc 5-10 min
9X0X2	Ol dig e/m svc 11-20 min
9X0X3	Ol dig e/m svc 21+ min
9XXX0	Ther ivntj ea addl 15 min

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O. Comment Solicitation on Opportunities for Bundled Payments Under the PFS

Under the PFS, Medicare typically makes a separate payment for each individual service furnished to a beneficiary consistent with section 1848 of the Act, which requires CMS to establish payment for physicians' services based on the relative resources involved in furnishing the service. The statute defines ''services'' broadly, with reference to the uniform procedure coding system established by CMS for the purpose of Medicare FFS payments, called the Healthcare Common Procedure Coding System (HCPCS). There are sets of HCPCS codes that represent health care procedures, supplies, medical equipment, products, and services. The majority of physicians' services for which payment is made under the PFS are described using HCPCS Level I codes and descriptors that are the AMA's Current Procedural Terminology (CPT) code set. CPT codes generally describe an individual item or service, while some codes describe a combination of services (a procedure and imaging guidance, for example) bundled together. Some HCPCS codes explicitly encompass multiple services (global surgery codes, for example), and the PFS payment for some services is reduced when a combination of services is furnished to the same patient on the same day (through multiple procedure payment reduction policies). However, payment for most services under the PFS is made based on rates established for individual services, each described by a CPT code. Identifying and developing appropriate payment policies that aim to achieve better care and improved health for Medicare beneficiaries is a priority for CMS. Consistent with that goal, we are interested in exploring new options for establishing PFS payment rates or adjustments for services that are furnished together. For purposes of this discussion, we will refer to the circumstances where a set of services is grouped together for purposes of ratesetting and payment as ''bundled payment.''

One of the mechanisms through which we support innovative payment and service delivery models, for Medicare and other beneficiaries, is through CMS' Center for Medicare and Medicaid Innovation (the Innovation Center). The Innovation Center is currently testing models in which payment for physicians' services is bundled on a per-beneficiary population basis, or is based on episodes of care that usually begin with a triggering event and extend for a specified period of time thereafter. An example of a model in which payment is made on a per-beneficiary population basis is Comprehensive Primary Care Plus (CPC+), in which participating practices receive prospective per-beneficiary care management fees and Comprehensive Primary Care Payments for certain primary care services such as chronic care management and evaluation and management services. An example of an episode payment model is the Oncology Care Model (OCM), in which participating physician practices receive a per-beneficiary Monthly Enhanced Oncology Services payment for care management and care coordination surrounding chemotherapy administration to cancer patients. We are actively exploring the extent to which these basic principles of bundled payment, such as establishing per-beneficiary payments for multiple services or condition-specific episodes of care, can be applied within the statutory framework of the PFS.

We are seeking public comments on opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the PFS and better align Medicare payment policies with CMS's broader goal of achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system. We believe that the statute, while requiring CMS to pay for physicians' services based on the relative resources involved in furnishing the service, allows considerable flexibility for developing payments under the PFS.

P. Payment for Evaluation and Management (E/M) Visits

1. Background

a. E/M Visits Coding Structure

Physicians and other practitioners who are paid under the PFS bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. These CPT codes are broadly referred to as E/M visit codes and have three key components within their code descriptors: History of present illness (History), physical examination (Exam), and medical decision-making (MDM).[80]

The CPT code descriptors recognize counseling, care coordination, and the nature of the presenting problem as additional service components, but these are contributory factors in determining which code to report.[81] Per the CPT code descriptors, counseling and/or care coordination are provided consistent with the nature of the problem and the patient's and/or family's needs. Counseling and care coordination are not required at every patient encounter and can be accounted for in separate coding.[82]

As finalized in the CY 2019 PFS final rule, the amount of time spent by the billing practitioner is not a determining factor in code level selection unless (1) counseling and care coordination dominate the visit, in which case time becomes the key factor in determining visit level; and/or (2) the service is a prolonged (or beginning in 2021, ''extended'') (83 FR 59630) E/M visit. Typical times for each level of E/M visit are included in each of the CPT code descriptors, are used for PFS rate setting purposes, and provide a reference point for the reporting of prolonged visits. Separate add-on codes describe, and can be reported for, visits that take prolonged (or beginning in 2021, ''extended'') (83 FR 59630) amounts of time.

There are 3 to 5 E/M visit code levels, depending upon site of service and the extent of the three components of history, exam, and MDM. For example, there are 3 to 4 levels of E/M visit codes in the inpatient hospital and nursing facility settings based on a relatively narrow range of complexity in those settings. In contrast, there are 5 levels of E/M visit codes in the office or other outpatient setting based on a broader range of complexity in those settings.

PFS payment rates for E/M visit codes generally increase with the level of visit billed, although in the CY 2019 PFS final rule (83 FR 59638), for reasons discussed below, we finalized the assignment of a single payment rate for levels 2 through 4 office/outpatient E/M visits beginning in CY 2021. As for all services under the PFS, the payment rates for E/M visits are based on the work (time and intensity), practice expense, and malpractice expense resources required to furnish the typical case of the service.

In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise

[80] 2019 CPT Codebook, Evaluation and Management, pp. 6–13.

[81] 2019 CPT Codebook, Evaluation and Management, pp. 6–13.

[82] 2019 CPT Codebook, Evaluation and Management, pp. 4–56.

approximately 20 percent of allowed charges for PFS services. Within the E/M services represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed services for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include both primary care practitioners and certain specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology and otolaryngology, tend to bill more E/M visits on the same day as they bill minor procedures.

b. E/M Documentation Guidelines

For CY 2019 and 2020, when coding and billing E/M visits to Medicare, practitioners may use one of two versions of the E/M Documentation Guidelines for a patient encounter, commonly referenced based on the year of their release: the ''1995'' or ''1997'' E/M Documentation Guidelines (hereafter, the 1995 and 1997 Guidelines).[83] These Guidelines specify the medical record information within each of the three key components (such as number of body systems reviewed) that serves as support for billing a given level of E/M visit. The 1995 and 1997 Guidelines are very similar to the guidelines for E/M visits that currently reside within the AMA's CPT codebook for E/M visits. For example, the core structure of what comprises or defines the different levels of history, exam, and medical decision-making in the 1995 and 1997 Guidelines are the same as those in the CPT codebook. However, the 1995 and 1997 Guidelines include extensive examples of clinical work that comprise different levels of medical decision-making that do not appear in the AMA's CPT codebook. Also, the 1995 and 1997 Guidelines do not contain references to preventive care that appear in the AMA's CPT codebook. We provide an example of how the 1995 and 1997 Guidelines distinguish between level 2 and level 3 E/M visits in Table 25.

TABLE 25—KEY COMPONENT DOCUMENTATION REQUIREMENTS FOR LEVEL 2 VS. 3 E/M VISIT

Key component *	Level 2 (1995)	Level 3 (1995)	Level 2 (1997)	Level 3 (1997)
History (History of Present Illness or HPI).	Review of Systems (ROS) n/a.	Problem Pertinent ROS: Inquires about the system directly related to the problem(s) identified in the HPI.	No change from 1995	No change from 1995.
Physical Examination (Exam).	A limited examination of the affected body area or organ system.	A limited examination of the affected body area or organ system and other symptomatic or related organ system(s).	General multi-system exam: Performance and documentation of one to five elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of one to five elements.	General multi-system exam: Performance and documentation of at least six elements in one or more organ system(s) or body area(s). Single organ system exam: Performance and documentation of at least six elements.
Medical Decision Making (MDM). Measured by: **	Straightforward:	Low complexity:	No change from 1995.	
1. Problem—Number of diagnoses/treatment options.	1. Minimal	1. Limited.		
2. Data—Amount and/or complexity of data to be reviewed.	2. Minimal or no data review.	2. Limited data review.		
3. Risk—Risk of complications and/or morbidity or mortality.	3. Minimal risk	3. Low risk.		

* For certain settings and patient types, each of these three key components must be met or exceeded (for example, new patients; initial hospital visits). For others, only two of the three key components must be met or exceeded (for example, established patients, subsequent hospital or other visits).

** Two of three met or exceeded.

According to both Medicare claims processing manual instructions and CPT coding rules, when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter (or, in the case of inpatient E/M services, the floor time) the duration of the visit can be used as an alternative basis to select the appropriate E/M visit level (Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.C available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf; see* also 2019 CPT Codebook Evaluation and Management Services Guidelines, page 10). Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Instruct physicians to select the code for the service based

[83] See *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf*; *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf*; and the Evaluation and Management Services guide at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf.*

upon the content of the service. The duration of the visit is an ancillary factor and does not control the level of the service to be billed unless more than 50 percent of the face-to-face time (for non-inpatient services) or more than 50 percent of the floor time (for inpatient services) is spent providing counseling or coordination of care as described in subsection C.'' Subsection C states that ''the physician may document time spent with the patient in conjunction with the medical decision-making involved and a description of the coordination of care or counseling provided. Documentation must be in sufficient detail to support the claim.'' The example included in subsection C further states, ''The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail to justify the selection of the specific code if time is the basis for selection of the code.''

Both the 1995 and 1997 Guidelines address time, stating that, ''In the case where counseling and/or coordination of care dominates (more than 50 percent of) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), time is considered the key or controlling factor to qualify for a particular level of E/M services.'' The Guidelines go on to state that, ''If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.'' [84] Additional manual provisions regarding E/M visits are housed separately within Medicare's internet-Only Manuals, and are not contained within the 1995 or 1997 Guidelines.

In accordance with section 1862(a)(1)(A) of the Act, which requires services paid under Medicare Part B to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, medical necessity is a prerequisite to Medicare payment for E/M visits. Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1.B states, ''Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported.''

c. Summary of Changes to Coding, Payment and Documentation of Office/Outpatient E/M Visits Finalized for CY 2021 in the CY 2019 PFS Final Rule

In the CY 2019 PFS final rule (83 FR 59452 through 60303), we finalized a number of coding, payment, and documentation changes under the PFS for office/outpatient E/M visits (CPT codes 99201–99215) to reduce administrative burden, improve payment accuracy, and update this code set to better reflect the current practice of medicine. In summary, we finalized the following policy changes for office/outpatient E/M visits under the PFS effective January 1, 2021:

- Reduction in the payment variation for office/outpatient E/M visit levels by paying a single rate (also referred to as a blended rate) for office/outpatient E/M visit levels 2 through 4 (one rate for established patients and another rate for new patients), while maintaining the payment rate for office/outpatient E/M visit level 5 in order to better account for the care and needs of complex patients. Practitioners will still report the appropriate code for the level of service they furnished, since we did not replace these CPT codes with HCPCS G codes and will continue to use typical times associated with each individual CPT code when time is used to document the office/outpatient E/M visit.
- Permitting practitioners to choose to document office/outpatient E/M level 2 through 5 visits using MDM or time, or the current framework based on the 1995 or 1997 Guidelines.
- As a corollary to the uniform payment rate for level 2–4 E/M visits, when using MDM or the current framework to document the office/outpatient E/M visit, a minimum supporting documentation standard associated with level 2 office/outpatient E/M visits will apply. For these cases, Medicare will require information to support a level 2 office/outpatient E/M visit code for history, exam, and/or MDM.
- When time is used to document, practitioners will document the medical necessity of the office/outpatient E/M visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary. The required face-to-face time will be the typical time for the reported code, except for extended or prolonged visits where extended or prolonged times will apply.
- Implementation of HCPCS add-on G codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care (HCPCS codes GPC1X and GCG0X, respectively). These codes were finalized in order to reflect the differential resource costs associated with performing certain types of office/outpatient E/M visits. These codes will only be reportable with office/outpatient E/M level 2 through 4 visits.
- Adoption of a new ''extended visit'' add-on G code (HCPCS code GPRO1) for use only with office/outpatient E/M level 2 through 4 visits, to account for the additional resources required when practitioners need to spend extended time with the patient for these visits. The existing prolonged E/M codes can continue to be used with levels 1 and 5 office/outpatient E/M visits.

We stated that we believed these policies would allow practitioners greater flexibility to exercise clinical judgment in documentation so they can focus on what is clinically relevant and medically necessary for the beneficiary. We believed these policies will reduce a substantial amount of administrative burden (83 FR 60068 through 60070) and result in limited specialty-level redistributive impacts (83 FR 60060). We stated our intent to continue engaging in further discussions with the public over the next several years to potentially further refine our policies for 2021. We finalized the coding, payment, and documentation changes to reduce administrative burden, improve payment accuracy, and update the code set to better reflect the current practice of medicine.

2. Continued Stakeholder Feedback

In January and February 2019, we hosted a series of structured listening sessions on the forthcoming changes that CMS finalized for office/outpatient E/M visit coding, documentation and payment for CY 2021. These sessions provided an opportunity for CMS to gain further input and information from the wide range of affected stakeholders on these important policy changes. Our goal was to continue to listen and consider perspectives from individual practicing clinicians, specialty associations, beneficiaries and their advocates, and other interested stakeholders to prepare for implementation of the office/outpatient

[84] Page 16 of the 1995 E/M guidelines and page 48 of the 1997 guidelines.

E/M visit policies that we finalized for CY 2021.

In these listening sessions, although stakeholders supported our intention to reduce burdensome, clinically outdated documentation requirements, they noted that in response to the office/outpatient E/M visit policies CMS finalized for CY 2021, the AMA/CPT established the Joint AMA CPT Workgroup on E/M to develop an alternative solution. This workgroup developed an alternative approach, similar to the one we finalized, for office/outpatient E/M coding and documentation. That approach was approved by the CPT Editorial Panel in February 2019, with an effective date of January 1, 2021 and is available on the AMA's website at *https://www.ama-assn.org/cpt-evaluation-and-management.*

Effective January 1, 2021, the CPT Editorial Panel adopted revisions to the office/outpatient E/M code descriptors, and substantially revised both the CPT prefatory language and the CPT interpretive guidelines that instruct practitioners on how to bill these codes. The AMA has approved an accompanying set of interpretive guidelines governing and updating what determines different levels of MDM for office/outpatient E/M visits. Some of the changes made by the CPT Editorial Panel parallel our finalized policies for CY 2021, such as the choice of time or MDM in determination of code level. Other aspects differ, such as the number of code levels retained, presumably for purposes of differential payment; the times, and inclusion of all time spent on the day of the visit; and elimination of options such as the use of history and exam or time in combination with MDM, to select code level.

Many stakeholders have continued to express objections to our assignment of a single payment rate to level 2–4 office/outpatient E/M visits stating that this inappropriately incentivizes multiple, shorter visits and seeing less complex patients. Many stakeholders also stated that the purpose and use of the HCPCS add-on G codes that we established for primary care and non-procedural specialized medical care remain ambiguous, expressed concern that the codes are potentially contrary to current law prohibiting specialty-specific payment, and asserted that Medicare's coding approach is unlikely to be adopted by other payers.

In meetings with stakeholders since we issued the CY 2019 PFS final rule, some stakeholders suggested that only time should be used to select the service level because time is easy to audit, simple to document, and better accounts for patient complexity, in comparison to the CPT Editorial Panel revised MDM interpretive guidance. These stakeholders stated that the implementation of the CPT Editorial Panel revised MDM interpretive guidance will result in the likely increase in the selection of levels 4 and 5, relative to current typical coding patterns. They suggested that to more accurately distinguish varying levels of patient complexity, either the visit levels should be recalibrated so that levels 4 and 5 no longer represent the most often billed visit, or a sixth level should be added. In these meetings, some stakeholders also stated that the office/outpatient E/M codes fail to capture the full range of services provided by certain specialties, particularly primary care and other specialties that rely heavily on office/outpatient E/M services rather than procedures, systematically undervaluing primary care visits and visits furnished in the context of non-procedural specialty care, thereby creating payment disparities that have contributed to workforce shortages and beneficiary access challenges across a range of specialties. They reiterated that office/outpatient E/M visit codes have not been extensively examined since the creation of the PFS and recommended that CMS conduct an extensive research effort to revise and revalue office/outpatient E/M services through a major research initiative akin to that undertaken when the PFS was first established.

The AMA believes its approach will accomplish greater burden reduction, is more clinically intuitive and reflects the current practice of medicine, and is more likely to be adopted by all payers than the policies CMS finalized for CY 2021. The AMA has posted an estimate of the burden reduction associated with the policies approved at CPT on the AMA's website, available at *https://www.ama-assn.org/cpt-evaluation-and-management.*

Given the CPT coding changes that will take effect in 2021, the AMA RUC has conducted a resurvey and revaluation of the office/outpatient E/M visit codes, and provided us with its recommendations. We discuss our proposal to adopt the CPT coding for office/outpatient E/M visits below, noting that the CPT coding changes will also necessitate some changes to CMS' policies for CY 2021, due to forthcoming changes in code descriptors. In addition, we address revaluation of the codes, proposing new values for the codes as revised by CPT. We propose to assign separate payment rather than a blended rate, to each of the office/outpatient E/M visit codes (except CPT code 99201, which CPT is deleting) and the new prolonged visit add-on CPT code (CPT code 99XXX). We propose to delete the HCPCS add-on code we finalized last year for CY 2021 for extended visits (GPRO1). We propose to simplify, consolidate and revalue the HCPCS add-on codes we finalized last year for CY 2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow the new code to be reported with all office/outpatient E/M visit levels (not just levels 2 through 4). All of these changes would be effective January 1, 2021. We believe our proposed policies will further our ongoing effort to reduce administrative burden, improve payment accuracy, and update the office/outpatient EM visit code set to better reflect the current practice of medicine.

3. Proposed Policies for CY 2021 for Office/Outpatient E/M Visits

a. Office/Outpatient E/M Visit Coding and Documentation

For CY 2021, for office/outpatient E/M visits (CPT codes 99201–99215) we are proposing to adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA/CPT (*see https://www.ama-assn.org/cpt-evaluation-and-management*) because we believe it would accomplish greater burden reduction than the policies we finalized for CY 2021 and would be more intuitive and consistent with the current practice of medicine. We note that this includes deletion of CPT code 99201 (Level 1 office/outpatient visit, new patient), which the CPT Editorial Panel decided to eliminate as CPT codes 99201 and 99202 are both straightforward MDM and only differentiated by history and exam elements.

Under this new framework, history and exam would no longer select the level of code selection for office/outpatient E/M visits. Instead, an office/outpatient E/M visit would include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam would no longer apply, and these components would only be performed when, and to the extent medically necessary and clinically appropriate. Level 1 visits would only describe or include visits performed by clinical staff for established patients.

For levels 2 through 5 office/outpatient E/M visits, the code level reported would be decided based on

either the level of MDM (as redefined in the new AMA/CPT guidance framework) or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). Because we would no longer assign a blended payment rate (discussed below), we would no longer adopt the minimum supporting documentation associated with level 2 office/outpatient E/M visits, which we finalized as a corollary to the uniform payment rate for level 2–4 office/outpatient E/M visits when using MDM or the current framework to document the office/outpatient E/M visit.

We would adopt the new time ranges within the CPT codes as revised by the CPT Editorial Panel. We interpret the revised CPT prefatory language and reporting instructions to mean that there would be a single add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX) that would only be reported when time is used for code level selection and the time for a level 5 office/outpatient visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service. The long descriptor for CPT code 99XXX is *Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*. We demonstrate below how prolonged office/outpatient E/M visit time would be reported:

TABLE 26—TOTAL PROPOSED PRACTITIONER TIMES FOR OFFICE/OUTPATIENT E/M VISITS WHEN TIME IS USED TO SELECT VISIT LEVEL

Established patient office/outpatient E/M visit (total practitioner time, when time is used to select code level) (minutes)	CPT code
40–54	99215.
55–69	99215x1 and 99XXXx1.
70–84	99215x1 and 99XXXx2.
85 or more	99215x1 and 99XXXx3 or more for each additional 15 mintues.
New patient office/outpatient E/M visit (total practitioner time, when time is used to select code level) (minutes)	**CPT code**
60–74	99205.
75–89	99205x1 and 99XXXx1.
90–104	99205x1 and 99XXXx2.
105 or more	99205x1 and 99XXXx3 or more for each additional 15 minutes.

We are proposing to adopt our interpretation of the revised CPT prefatory language and reporting instructions, that CPT codes 99358–9 (Prolonged E/M without Direct Patient Contact) would no longer be reportable in association or ''conjunction'' with office/outpatient E/M visits. In other words, when using time to select office/outpatient E/M visit level, any additional time spent by the reporting practitioner on a prior or subsequent date of service (such as reviewing medical records or test results) could not count towards the required times for reporting CPT codes 99202–99215 or 99XXX, or be reportable using CPT codes 99358–9. This interpretation would be consistent with the way the office/outpatient E/M visit codes were resurveyed, where the AMA/RUC instructed practitioners to consider all time spent 3 days prior to, or 7 days after, the office/outpatient E/M visit (*see* below for a discussion of revaluation proposals). Moreover we note that CPT codes 99358–9 describe time spent beyond the ''usual'' time (CPT prefatory language), and it is not clear what would comprise ''usual'' time given the new time ranges for the office/outpatient E/M visit codes and new CPT code 99XXX (prolonged office/outpatient E/M visit). New CPT prefatory language specifies, ''For prolonged services on a date other than the date of a face-to-face encounter, including office or other outpatient services (99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215), see 99358, 99359 . . . Do not report 99XXX in conjunction with . . . 99358, 99359''. We do not believe CPT code 99211 should be included in this list of base codes since it will only include clinical staff time. Also given that CPT codes 99358, 99359 can be used to report practitioner time spent on any date (the date of the visit or any other day), the CPT reporting instruction ''see 99358, 99359'' seems circular. The new prefatory language seems unclear regarding whether CPT codes 99358, 99359 could be reported instead of, or in addition to, CPT code 99XXX, and whether the prolonged time would have to be spent on the visit date, within 3 days prior or 7 days after the visit date, or outside of this new 10-day window relevant for the base code. We are seeking public input on this proposal and whether it would be appropriate to interpret the CPT reporting instructions for CPT codes 99358–9 as proposed, as well as how this interpretation may impact valuation. We believe CPT codes 99358 and 99359 may need to be redefined, resurveyed and revalued. After internal review, we believe that when time is used to select visit level, having one add-on code (CPT code 99XXX) instead of multiple add-on codes for additional time may be administratively simpler and most consistent with our goal of documentation burden reduction.

HCPCS code GPRO1 (extended office/outpatient E/M time) would no longer be needed because the time described by this code would instead be described by a level 3, 4 or 5 office/outpatient E/M visit base code and, if applicable, the single new add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX). Therefore, we propose to delete HCPCS code GPRO1 for CY 2021. We propose to adopt the AMA/CPT prefatory language that lists qualifying activities that could be included when time is used to select the visit level. Alternatively, if MDM is used to choose the visit level, time would not be relevant to code selection.

b. Office/Outpatient E/M Visit Revaluation (CPT Codes 99201 Through 99215)

We have received valuation recommendations from the AMA RUC for the revised office/outpatient E/M codes (CPT codes 99201 through 99215) following completion of its survey and revaluation process for these codes. Although these codes do not take effect until CY 2021, we believe that it is appropriate to follow our usual process of addressing the valuation of the revised office/outpatient E/M codes through rulemaking after we receive the RUC recommendations. Additionally, establishing values for the new codes through rulemaking this year will allow more time for clinicians to make any necessary process and systems adjustments before they begin using the codes. In recent years, we have considered how best to update and revalue the office/outpatient E/M codes as they represent a significant proportion of PFS expenditures.

MedPAC has had longstanding concerns that office/outpatient E/M services are undervalued in the PFS, and in its March 2019 Report to Congress, further asserted that the office/outpatient E/M code set has become passively devalued as values of these codes have remained unchanged, while the coding and valuation for other types of services under the fee schedule have been updated to reflect changes in medical practice (*see* pages 120 through 121 at *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch4_sec.pdf?sfvrsn=0*).

In April 2019, the RUC provided us the results of its review, and recommendations for work RVUs, practice expense inputs and physician time (number of minutes) for the revised office/outpatient E/M code set. Please note that these proposed changes in coding and values are for the revised office/outpatient E/M code set and a new 15-minute prolonged services code. That code set is effective beginning in CY 2021, and the proposed values would go into effect with those codes as of January 1, 2021.

We are proposing to adopt the RUC-recommended work RVUs for all of the office/outpatient E/M codes and the new prolonged services add-on code. Specifically, we are proposing a work RVU of 0.93 for CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15–29 minutes of total time is spent on the date of the encounter*), a work RVU of 1.6 for CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30–44 minutes of total time is spent on the date of the encounter*), a work RVU of 2.6 for CPT code 99204 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45–59 minutes of total time is spent on the date of the encounter*), a work RVU of 3.5 for CPT code 99205 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60–74 minutes of total time is spent on the date of the encounter. (For services 75 minutes or longer, see Prolonged Services 99XXX)*), a work RVU of 0.18 for CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal)*), a work RVU of 0.7 for CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*), a work RVU of 1.3 for CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter),* a work RVU of 1.92 for CPT code 99214 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30–39 minutes of total time is spent on the date of the encounter*), a work RVU of 2.8 for CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40–54 minutes of total time is spent on the date of the encounter. (For services 55 minutes or longer, see Prolonged Services 99XXX)*) and a work RVU of 0.61 for CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*).

Regarding the RUC recommendations for practice expense inputs for these codes, we are proposing to remove equipment item ED021 (computer, desktop, with monitor), as we do not believe that this item would be allocated to the use of an individual patient for an individual service; rather, we believe this item is better characterized as part of indirect costs similar to office rent or administrative expenses.

The information we reviewed on the RUC valuation exercise was based on an extensive survey the RUC conducted of over 50 specialty societies. For purposes of valuation, survey respondents were asked to consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a time frame of 3 days prior to the visit and 7 days after, respectively. This is different from the way codes are usually surveyed by the RUC for purposes of valuation, where pre-, intra-, and post-service time were surveyed, but not within a specific time frame. The RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time. The RUC's approach sometimes results in two conflicting sets of times: The component times as surveyed and the total time as surveyed. Although we are proposing to adopt the RUC-recommended times as explained below, we are seeking comment on how CMS should address the discrepancies in times, which have implications both for for valuation of individual codes and for PFS ratesetting in general, as the intra-service times and total times are used as references for valuing many other services under the PFS and that the programming used for PFS ratesetting requires that the

component times sum to the total time. Specifically, we request comment on which times should CMS use, and how we should resolve differences between the component and total times when they conflict. Table 27A illustrates the surveyed times for each service period and the surveyed total time. It also shows the actual total time if summed from the component times.

TABLE 27A—RUC-RECOMMENDED PRE-, INTRA-, POST-SERVICE TIMES, RUC-RECOMMENDED TOTAL TIMES FOR CPT CODES 99202–99215 AND ACTUAL TOTAL TIME

HCPCS	Pre-service time	Intra-service time	Immediate post-service time	Actual total time	RUC-recommended total time
99202	2	15	3	20	22
99203	5	25	5	35	40
99204	10	40	10	60	60
99205	14	59	15	88	85
99211	.....	5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

Table 27B summarizes the current office/outpatient E/M services code set, and the new prolonged services code physician work RVUs and total time compared to what CMS finalized in CY 2019 for CY 2021, and the RUC-recommended work RVU and total time.

TABLE 27B—SIDE BY SIDE COMPARISON OF WORK RVUS AND PHYSICIAN TIME FOR THE OFFICE/OUTPATIENT E/M SERVICES CODE SET, AND THE NEW PROLONGED SERVICES CODE

[Current versus revised]

HCPCS code	Current total time (mins)	Current work RVU	CY 2021 total time (mins)	CY 2021 work RVU	RUC rec total time (mins)	RUC rec work RVU
99201	17	0.48	17	0.48	N/A	N/A
99202	22	0.93	22	1.76	22	0.93
99203	29	1.42	29	1.76	40	1.6
99204	45	2.43	45	1.76	60	2.6
99205	67	3.17	67	3.17	85	3.5
99211	7	0.18	7	0.18	7	0.18
99212	16	0.48	16	1.18	18	0.7
99213	23	0.97	23	1.18	30	1.3
99214	40	1.5	40	1.18	49	1.92
99215	55	2.11	55	2.11	70	2.8
99XXX	N/A	N/A	N/A	N/A	15	0.61

The RUC recommendations reflect a rigorous robust survey approach, including surveying over 50 specialty societies, demonstrate that office/outpatient E/M visits are generally more complex, for most clinicians. In the CY 2019 PFS final rule, we finalized for CY 2021 a significant reduction in the payment variation in office/outpatient E/M visit levels by paying a single blended rate for E/M office/outpatient visit levels 2 through 4 (one for established and another for new patients). We also maintained the separate payment rates for E/M office/outpatient level 5 visits in order to better account for the care and needs of particularly complex patients. We believed that the single blended payment rate for E/M office/outpatient visit levels 2–4 better accounted for the resources associated with the typical visit. After reviewing the RUC recommendations, in conjunction with the revised code descriptors and documentation guidelines for CPT codes 99202 through 99215, we believe codes and recommended values would more accurately account for the time and intensity of office/outpatient E/M visits than either the current codes and values or the values we finalized in the CY 2019 PFS final rule for CY 2021. Therefore, we are proposing to establish separate values for Levels 2–4 office/outpatient E/M visits for both new and established patients rather than continue with the blended rate. We are proposing to accept the RUC-recommended work and time values for the revised office/outpatient E/M codes without refinement for CY 2021. With regard to the RUC's recommendations for practice expense inputs, we are proposing to remove equipment item ED021 (computer, desktop, with monitor), as this item is included in the overhead costs. Note that these changes to codes and values would go into effect January 1, 2021.

c. Simplification, Consolidation and Revaluation of HCPCS Codes GCG0X and GPC1X

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes would more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we believe that the revalued office/outpatient E/M code set itself still does not appropriately reflect differences in resource costs between certain types of office/outpatient E/M visits. In the CY 2019 PFS proposed rule we articulated that, based on stakeholder comments, clinical examples, and our review of the literature on office/outpatient E/M

services, there are three types of office/outpatient E/M visits that differ from the typical office/outpatient E/M visit and are not appropriately reflected in the current office/outpatient E/M code set and valuation. These three types of office/outpatient E/M visits can be distinguished by the mode of care provided and, as a result, have different resource costs. The three types of office/outpatient E/M visits that differ from the typical office/outpatient E/M service are (1) separately identifiable office/outpatient E/M visits furnished in conjunction with a global procedure, (2) primary care office/outpatient E/M visits for continuous patient care, and (3) certain types of specialist office/outpatient E/M visits. We proposed, but did not finalize, the application of an MPPR to the first category of visits, to account for overlapping resource costs when office/outpatient E/M visits were furnished on the same day as a 0-day global procedure. To address the shortcomings in the E/M code set in appropriately describing and reflecting resource costs for the other two types of office/outpatient E/M visits, we proposed and finalized the two HCPCS G codes: HCPCS code GCG0X (*Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established*) which describes the inherent complexity associated with certain types of specialist visits and GPC1X (*Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established*), which describes additional resources associated with primary care visits.

Although we finalized two separate codes, we valued both HCPCS codes GCG0X and GPC1X via a crosswalk to 75 percent of the work and time value of CPT code 90785 (*Interactive complexity (List separately in addition to the code for primary procedure*)). Interactive complexity is an add-on code that may be billed when a psychotherapy or psychiatric service requires more work due to the complexity of the patient, and we believed that 75 percent of its work and time values accurately captured the additional resource costs of primary care office/outpatient visits and certain types of specialty office/outpatient visits when billed with the single, blended payment rate for office/outpatient E/M visit levels 2–4.

In the CY 2019 PFS final rule, we stated that, due to the variation among the types of visits performed by certain specialties, we did not believe that the broad office/outpatient E/M code set captured the resource costs associated with furnishing primary care and certain types of specialist visits (FR 83 59638). As we stated above, we believe that the revised office/outpatient E/M code set and RUC-recommended values more accurately reflect the resources associated with a typical visit. However, we believe the typical visit described by the revised code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits.

As such, we believe that there is still a need for add-on coding because the revised office/outpatient E/M code set does not recognize that there are additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits. However, based on previous public comments and ongoing engagement with stakeholders, we understand the need for the add-on code(s) and descriptor(s) to be easy to understand and report when appropriate, including in terms of medical record documentation and billing. We also want to make it clear that the add-on coding is not intended to reflect any difference in payment based on the billing practitioner's specialty, but rather the recognition of different per-visit resource costs based on the kinds of care the practitioner provides, regardless of their specialty. Therefore, we are proposing to simplify the coding by consolidating the two add-on codes into a single add-on code and revising the single code descriptor to better describe the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

We are proposing to revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X. The proposed descriptor for GPC1X appears in Table 28. We are seeking comment from the public and stakeholders regarding these proposed changes, particularly the proposed new code descriptor for GPC1X and whether or not more than one code, similar to the policy finalized last year, would be necessary or beneficial.

We have also reconsidered the appropriate valuation for this HCPCS add-on G-code in the context of the revised office/outpatient E/M service code set and proposed values. Upon further review and in light of the other proposed changes to the office/outpatient E/M service code set, we believe that valuing the add-on code at 75 percent of CPT code 90785 would understate the additional inherent intensity associated with furnishing primary care and certain types of specialty visits. As CPT code 90785 also describes additional work associated with certain psychotherapy or psychiatric services, we believe its work and time values are the most appropriate crosswalk for the revised HCPCS code GPC1X. Therefore, we are proposing to value HCPCS code GPC1X at 100 percent of the work and time values for CPT code 90785, and proposing a work RVU of 0.33 and a physician time of 11 minutes. We are also proposing that this HCPCS add-on G code could be billed as applicable with every level of office and outpatient E/M visit, and that we would revise the code descriptor to reflect that change. See Table 28 for the proposed changes to the code descriptor. We note that if the CPT Editorial Panel makes any further changes to the office and outpatient E/M codes and descriptors, or creates one or more CPT codes that duplicate this add-on code, or if the RUC and/or stakeholders or other public commenters recommend values for these or other related codes, we would consider them through subsequent rulemaking.

TABLE 28—PROPOSED REVALUATION OF HCPCS ADD-ON G CODE FINALIZED FOR CY 2021

HCPCS code	Proposed code descriptor revisions	FR 2019 total time (mins)	FR 2019 work RVU	Proposed total time (mins)	Proposed work RVU
GPC1X	*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).*	8.25	0.25	11	0.33

d. Valuation of CPT Code 99xxx (Prolonged Office/Outpatient E/M)

The RUC also provided a recommendation for new CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services*). The RUC recommended 15 minutes of physician time and a work RVU of 0.61. We are proposing to delete to the HCPCS add-on code we finalized last year for CY 2021 for extended visits (GPRO1) and adopt the new CPT code 99XXX. Further, as discussed above we are proposing to accept the RUC recommended values for CPT code 99XXX without refinement.

We are seeking comment on these proposals, as well as any additional information stakeholders can provide on the appropriate valuation for these services.

e. Implementation Timeframe

We propose that these policy changes for office/outpatient E/M visits would be effective for services furnished starting January 1, 2021. We believe this would allow sufficient time for practitioner and provider education and further feedback; changes in clinical workflows, EHRs and any other impacted systems; and corresponding changes that may be made by other payers. In summary, we propose to adopt the following policies for office/outpatient E/M visits effective January 1, 2021:

- Separate payment for the five levels of office/outpatient E/M visit CPT codes, as revised by the CPT Editorial Panel effective January 1, 2021 and resurveyed by the AMA RUC, with minor refinement. This would include deletion of CPT code 99201 (Level 1 new patient office/outpatient E/M visit) and adoption of the revised CPT code descriptors for CPT codes 99202–99215;
- Elimination of the use of history and/or physical exam to select among code levels;
- Choice of time or medical decision making to decide the level of office/outpatient E/M visit (using the revised CPT interpretive guidelines for medical decision making);
- Payment for prolonged office/outpatient E/M visits using the revised CPT code for such services, including separate payment for new CPT code 99xxx and deletion of HCPCS code GPRO1 (extended office/outpatient E/M visit) that we previously finalized for 2021;
- Revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X; and
- Increase in value for HCPCS code GCG1X and allowing it to be reported with all office/outpatient E/M visit levels.

f. Global Surgical Packages

In addition to their recommendations regarding physician work, time, and practice expense for office/outpatient E/M visits, the AMA RUC also recommended adjusting the office/outpatient E/M visits for codes with a global period to reflect the changes made to the values for office/outpatient E/M visits. Procedures with a 10- and 90-day global period have post-operative visits included in their valuation. These post-operative visits are valued with reference to values for the E/M visits and each procedure has at least a half of an E/M visit included the global period. However, these visits are not directly included in the valuation. Rather, work RVUs for procedures with a global period are generally valued using magnitude estimation.

In the CY 2015 PFS final rule, we discussed the challenges of accurately accounting for the number of visits included in the valuation of 10- and 90-day global packages. (79 FR 67548, 67582.) We finalized a policy to change all global periods to 0-day global periods, and to allow separate payment for post-operative follow-up E/M visits. Our concerns were based on a number of key points including: The lack of sufficient data on the number of visits typically furnished during the global periods, questions about whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and concerns about how our global payment policies could affect the services that are actually furnished. In finalizing a policy to transform all 10- and 90-day global codes to 0-day global codes in CY 2017 and CY 2018, respectively, to improve the accuracy of valuation and payment for the various components of global packages, including pre- and post-operative visits and the procedure itself, we stated that we were adopting this policy because it is critical that PFS payment rates be based upon RVUs that reflect the relative resources involved in furnishing the services. We also stated our belief that transforming all 10- and 90-day global codes to 0-day global packages would:

- Increase the accuracy of PFS payment by setting payment rates for individual services that more closely reflect the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global packages; and
- Facilitate the availability of more accurate data for new payment models and quality research.

Section 523(a) of MACRA added section 1848(c)(8)(A) of the Act, which

prohibited the Secretary from implementing the policy described above, which would have transformed all 10-day and 90-day global surgery packages to 0-day global packages. Section 1848(c)(8)(B) of the Act, which was also added by section 523(a) of the MACRA, required us to collect data to value surgical services. Section 1848(c)(8)(B)(i) of the Act requires us to develop a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery and furnished during the global period, as appropriate. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General shall audit a sample of the collected information to verify its accuracy. Section 1848(c)(8)(C) of the Act, which was also added by section 523(a) of the MACRA, requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

Resource-based valuation of individual physicians' services is a critical foundation for Medicare payment to physicians. It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources used in furnishing specific services to make appropriate payment and preserve relativity among services. For global surgical packages, this requires using objective data on all of the resources used to furnish the services that are included in the package. Not having such data for some components may significantly skew relativity and create unwarranted payment disparities within the PFS. The current valuations for many services valued as global packages are based upon the total package as a unit rather than by determining the resources used in furnishing the procedure and each additional service/visit and summing the results. As a result, we do not have the same level of information about the components of global packages as we do for other services. To value global packages accurately and relative to other procedures, we need accurate information about the resources—work, PEs and malpractice—used in furnishing the procedure, similar to what is used to determine RVUs for all services. In addition, we need the same information on the postoperative services furnished in the global period (and pre-operative services the day before for 90-day global packages).

In response to the MACRA amendments to section 1848(c)(8 of the Act), CMS required practitioners who work in practices that include 10 or more practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island to report using CPT 99024 on post-operative visits furnished during the global period for select procedures furnished on or after July 1, 2017. The specified procedures are those that are furnished by more than 100 practitioners and either are nationally furnished more than 10,000 times annually or have more than $10 million in annual allowed charges.

RAND analyzed the data collected from the post-operative visits through this claim-based reporting for the first year of reporting, July 1, 2017–June 30, 2018. They found that only 4 percent of procedures with 10-day global periods had any post-operative visits reported. While 71 percent of procedures with 90-day global periods had at least one associated post-operative visit, only 39 percent of the total post-operative visits expected for procedures with 90-day global periods were reported. (A complete report on this is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*).

In addition to the claims-based data collection, RAND collected data on the level of visits. They began with an attempt to collect data via a survey from all specialties as described in the 2017 final rule. Given the low rate of response from practitioners, we shifted the study and focused on three high-volume procedures with global periods that were common enough to likely result in a robust sample size: (1) Cataract surgery; (2) hip arthroplasty; and (3) complex wound repair. A total of 725 physicians billing frequently for cataract surgery, hip arthroplasty, and complex wound repair reported on the time, activities, and staff involved in 3,469 visits. Our findings on physician time and work from the survey were broadly similar to what we expected based on the Time File for cataract surgery and hip replacement and somewhat different for complex wound repair. (For the complete report, *see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*).

The third report in the series looks at ways we could consider revaluing procedures using the collected data. To provide us with estimates to frame a discussion, RAND modeled how valuation for procedures would change by adjusting work RVUs, physician time, and direct PE inputs based on the difference between the number of post-operative visits observed via claims-based reporting and the expected number of post-operative visits used during valuation. RAND looked at three types of changes: (1) Updated work RVUs based on the observed number of post-operative visits measured four ways (median, 75th percentile, mean, and modal observed visits); (2) Allocated PE RVUs reflecting direct PE inputs updated to reflect the median number of reported post-operative visits; and (3) Modeled total RVUs reflecting (a) updated work RVUs, (b) updated physician time, and (c) updated direct PE inputs, and including allocated PE and malpractice RVUs. This report is designed to inform further conversations about how to revalue global procedures. (For the complete report, *see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Global-Surgery-Data-Collection-.html*.) We will give the public and stakeholders time to study the reports we are making available along with this rule and consider an appropriate approach to revaluing global surgical procedures. We also note that the Office of the Inspector General (OIG) has published a number of reports on this topic. We will continue to study and consider alternative ways to address the values for these services.

g. Comment Solicitation on Revaluing the Office/Outpatient E/M Visit Within TCM, Cognitive Impairment Assessment/Care Planning and Similar Services

We recognize there are services other than the global surgical codes for which the values are closely tied to the values of the office/outpatient E/M visit codes, such as transitional care management services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain ESRD monthly services (CPT codes 90951 through 90961); the Initial Preventive Physical Exam (G0438) and the Annual Wellness Visit (G0439). In future rulemaking, we may consider adjusting the RVUs for these services and are seeking public input on such a policy. We note that unlike the global surgical codes, these services always include an office/outpatient E/M visit(s) furnished by the reporting practitioner as part of the service, and it may therefore be appropriate to adjust their valuation commensurate with any

changes to the values for the revised codes for office/outpatient E/M visits. While some of these services do not involve an E/M visit, we valued them using a direct crosswalk to the RVUs assigned to an office/outpatient E/M visit(s) and for this reason they are closely tied to values for office/outpatient E/M visits.

We are also seeking comment on whether or not the public believes it would be necessary or beneficial to make systematic adjustments to other related PFS services to maintain relativity between these services and office/outpatient E/M visits. We are particularly interested in whether it would be beneficial or necessary to make corresponding adjustments to E/M codes describing visits in other settings, such as home visits, or to codes describing more specific kinds of visits, like counseling visits. For example, CPT code 99348 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family*) is commonly used to report home visits, and like CPT code 99214, the code describes approximately 45 minutes of time with the patient and has a work RVU of 1.56. Under the proposal to increase the work RVU of CPT code 99214 from 1.5 to 1.92, the proportional value of CPT code 99348 would decrease relative to the work RVU for CPT code 99214. To maintain the same proportional value to CPT code 99214, the work RVU for CPT code 99348 would need to increase from 1.56 to 2.00. We understand that certain other services, such as those that describe ophthalmological examination and evaluation, as well as psychotherapy visit codes, are used either in place of or in association with office/outpatient visit codes. For example, CPT code 92012 (*Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient*) currently has a work RVU of 0.92. Under the proposal to increase the work RVU of CPT code 99213 from 0.97 to 1.30, the proportional value of CPT code 92012 would decrease relative to the work RVU for CPT code 99213, as both codes describe around 30 minutes of work. To maintain the same proportional value to CPT code 99213, the work RVU for CPT code 92012 would need to increase from 0.92 to 1.23. Similarly, behavioral health professionals report several codes to describe psychiatric diagnostic evaluations and visits they furnish. When furnished with an evaluation and management service, practitioners report psychotherapy add-on codes instead of stand-alone psychotherapy codes that would otherwise be reported. Because the overall work RVUs for the combined service, including the value for the office/outpatient visit code, would increase under the proposal, we are interested in comments regarding whether or not it would be appropriate to reconsider the value of the psychotherapy codes, as well as the psychiatric diagnostic evaluations relative to the proposed values for the office/outpatient visit codes. Under the proposed revaluation of the office/outpatient E/M visits, the proportional value of CPT code 90834 (*Psychotherapy, 45 minutes with patient*) would decrease relative to work RVUs for CPT code 99214 plus CPT code 90836. The current work RVU for CPT code 99214 when reported with CPT code 90836 is 3.40 (1.90 + 1.50) and the current work RVU for CPT code 90834 is 2.0. Under the proposed revaluation of the office/outpatient E/M visits, the combined work RVU for CPT codes 99214 and 90836 would be 3.82 (1.90 + 1.92). In order to maintain the proportionate difference between these services, the work RVU for CPT code 90834 would increase from 2.00 to 2.25. Based on these three examples, we are seeking public comment on whether we should make similar adjustments to E/M codes in different settings, and other types of visits, such as counseling services.

III. Other Provisions of the Proposed Regulations

A. Changes to the Ambulance Physician Certification Statement Requirement

Under our ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, we are proposing to revise §§ 410.40 and 410.41. Importantly, we first clarify that these requirements apply to ambulance providers, as well as suppliers. The proposed revisions would give certain clarity to ambulance providers and suppliers regarding the physician or non-physician certification statement and add staff who may sign certification statements when the ambulance provider or supplier is unable to obtain a signed statement from the attending physician.

1. Exceptions to Certification Statement Requirement

Under section 1861(s)(7) of the Act, ambulance services are covered where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Currently, § 410.40(d) specifies the medical necessity requirements for both nonemergency, scheduled, repetitive ambulance services and nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis. In the final rule with comment period that appeared in the January 25, 1999 **Federal Register** (64 FR 3637) (hereinafter referred to as the ''January 25, 1999 final rule with comment period''), we stated that a physician certification statement (PCS) must be obtained as evidence that the attending physician has determined that other means of transportation are contraindicated and that the transport is medically necessary (64 FR 3639). In the final rule with comment period that appeared in the February 27, 2002 **Federal Register** (67 FR 9100) (hereinafter referred to as the ''February 27, 2002 final rule with comment period'') we added that a certification statement (hereinafter referred to as non-physician certification statement) could be obtained from other authorized staff should the attending physician be unavailable. (67 FR 9111)

Currently there are no circumstances, other than those specified at § 410.40(d)(3)(ii) and (iv), granting exceptions to the need for a PCS or non-physician certification statement, and we have received feedback from ambulance providers, suppliers, and their industry representatives (''stakeholders'') that various situations exist where the need for a PCS or non-physician certification is excessive, or at least redundant to similar existing documentation requirements. Two of the most prominent circumstances identified by the stakeholders include interfacility transports (IFTs), commonly referred to as hospital to hospital transports and specialty care transports (SCTs), and it has been requested that we incorporate additional exceptions into the regulatory framework.

Upon reviewing the need for a PCS and non-physician certification

statement, stakeholders' concerns, and our commitment to reducing the burden placed on providers and suppliers, we have determined that instead of incorporating additional exceptions, our efforts would be better served by minorly altering the structure of the existing regulatory framework. These changes are intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary.

To accomplish this, we are proposing to add a new paragraph (a) in § 410.40 in which we would define both PSCs, as well as non-physician certification statements. Therefore, we are proposing to redesignate existing paragraph (a) ''Basic rules'' as paragraph (b) and redesignate the remaining paragraphs, respectively. Most significantly, paragraph (d) ''Medical necessity requirements'' will be redesignated as paragraph (e).

For new proposed paragraph (a), the two definitions, PCSs and non-physician certification statements, would clarify that: (1) The focus is on the certification of the medical necessity provisions contained in proposed newly redesignated paragraph (e)(1); and (2) the form of the certification statement is not prescribed, thus affording maximum flexibility to ambulance providers and suppliers. Since the two definitions incorporate the requirement to obtain a certification of medical necessity, we are proposing a conforming change to newly redesignated paragraph (e)(2) to remove the language requiring that an order certifying medical necessity be obtained.

We have repeatedly been told by stakeholders that there are ample opportunities for ambulance providers and suppliers to convey the information required in the certification statement. Stakeholders have mentioned, for example, that for transports such as IFTs and SCTs other requirements of federal, state, or local law require them to obtain other documentation, such as Emergency Medical Treatment & Labor Act (EMTALA) forms and medical transport forms, that can serve the same purpose as the PCS or non-physician certification statement. There is every likelihood that other ambulance transports require similarly styled documentation that likewise could serve the same purpose.

To be clear, our regulations have never prescribed the precise form or format of this required documentation. To satisfy the requirements of section 1861(s)(7) of the Act, ambulance providers' and suppliers' focus should be on clearly documenting the threshold determination that other means of transportation are contraindicated and that the transport is medically necessary. The precise form or format by which that information is conveyed has never been prescribed. We aim here to ensure that ambulance providers and suppliers understand they have flexibility in the form by which they convey the requirements of proposed § 410.40(e), so long as that threshold determination is clearly expressed.

The definition of non-physician certification statement in proposed § 410.40(a) would incorporate the existing requirements that apply when an ambulance provider or supplier is unable to obtain a signed PCS from the attending physician and, instead, obtains a non-physician certification statement, including: (1) That the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished; (2) the employment requirements; and (3) the specific staff that can sign in lieu of the attending physician. Included within the proposed definition of non-physician certification statement, and as further discussed below, is an expansion of the list of staff who may sign when the attending physician is unavailable. In light of the staff being listed as part of the definition of non-physician certification statement proposed at § 410.40(a), we are proposing a corresponding change to proposed and newly redesignated paragraph (e)(3)(iii) to remove the reference to the staff currently listed within the paragraph. Moreover, in paragraphs (e)(3)(i) and (iv) we have proposed changes to refer to the newly redesignated paragraph (e) and in paragraph (e)(3)(v) we have proposed changes to refer to the newly defined terms in paragraph (a), specifically the physician or non-physician certification statement. Lastly, we are also proposing a corresponding change to § 410.41(c)(1) to add that ambulance providers or suppliers must indicate on the claims form that, ''when applicable, a physician certification statement or non-physician certification statement is on file.''

In the CY 2013 PFS final rule with comment period (77 FR 69161), we stated that the Secretary is the final arbiter of whether a service is medically necessary for Medicare coverage. We believe that the proposed changes would better enable contractors to establish the medical necessity of these transports by focusing more on the threshold medical necessity determination as opposed to the form or format of the documentation used. We do not anticipate that this clarification will alter the frequency of claim denials.

2. Addition of Staff Authorized To Sign Non-Physician Certification Statements

In the January 25, 1999 final rule with comment period (64 FR 3637), we finalized language at § 410.40 to require ambulance providers or suppliers, in the case of nonemergency unscheduled ambulance services (§ 410.40(d)(3)) to obtain a PCS. In that rule, we explained that: (1) Nonemergency ambulance service is a Medicare service furnished to a beneficiary for whom a physician is responsible, therefore, the physician is responsible for the medical necessity determination; and (2) the PCS will help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated (64 FR 3641). We further stated that we believed the requirement would help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries.

In that final rule with comment period, however, we also addressed the ability of ambulance providers or suppliers to obtain a written order from the beneficiary's attending physician within 48 hours after the transport to avoid unnecessary delays. We agreed with stakeholders that while it is reasonable to expect that an ambulance supplier could obtain a pretransport PCS for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports, and that it was not necessary that the ambulance suppliers have the PCS in hand prior to furnishing the service. To avoid unnecessary delays for unscheduled transports, we therefore finalized the requirement that required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished.

In the February 27, 2002 final rule with comment period (67 FR 9111), we noted that we had been made aware of instances in which ambulance suppliers, despite having provided ambulance transports, were, through no fault of their own, experiencing difficulty in obtaining the necessary PCS within the required 48-hour timeframe. We stated that the 48-hour period remained the appropriate period of time, but created alternatives for ambulance providers and suppliers unable to obtain a PCS. We finalized an alternative at § 410.40(d)(3)(iii) where ambulance providers and suppliers

unable to obtain a PCS from the attending physician could obtain a signed certification (*not* a physician certification statement) from certain other staff. At that time, we identified several staff members, including a physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), and a discharge planner as staff members able to sign such a non-physician certification statement. The only additional constraints are: (1) That the staff be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported; and (2) that the staff have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished.

In the intervening years, we have received feedback from stakeholders that other staff, such as licensed practical nurses (LPNs), social workers, and case managers, should be included in the list of staff that can sign a certification statement. Similar to the currently designated staff, we now believe that LPNs, social workers, and case managers who have personal knowledge of a beneficiary's condition at the time ambulance transport is ordered and the service is furnished have a skill set largely equal or similar to the other staff members. Thus, we are proposing as part of the new proposed definition of non-physician certification statement at § 410.40(a)(2)(iii) to add LPNs, social workers, and case managers to the list of staff who may sign a certification statement when the ambulance provider or supplier is unable to obtain a signed PCS from the attending physician. As with the staff currently listed in § 410.40(d)(3)(iii), LPNs, social workers, and case managers would need to be employed by the beneficiary's attending physician or the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported, and have personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. We also request comments on whether other staff should be included in this regulation, and request that commenters identify such staff's licensure and position and the reason it would be appropriate for such staff to sign a certification statement.

B. Proposal To Establish a Medicare Ground Ambulance Services Data Collection System

1. Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor, and other applicable adjustment factors as set forth at section 1834(l) of the Act and 42 CFR 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments are: (1) A 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments are: (1) A 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirement for Ground Ambulance Providers and Suppliers To Submit Cost and Other Information

Section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Such system must be designed to collect information: (1) Needed to evaluate the extent to which reported costs relate to payment rates under the AFS; (2) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a) of the Act; and (3) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

Section 1834(l)(17)(B)(i) of the Act requires the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system, including the representative sample defined at clause (ii).

Under section 1834(l)(17)(B)(ii) of the Act, not later than December 31, 2019, for the data collection for the first year and for each subsequent year through 2024, the Secretary must determine a representative sample to submit information under the data collection system. The sample must be representative of different types of ground ambulance providers and suppliers (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas), and not include an individual ground ambulance provider or supplier in the sample for 2 consecutive years, to the extent practicable.

Section 1834(l)(17)(C) of the Act requires that for each year, a ground ambulance provider or supplier identified by the Secretary in the representative sample as being required to submit information under the data collection system for a period for the year must submit to the Secretary the information specified under the system in a form and manner, and at a time specified by the Secretary.

Section 1834(l)(17)(D) of the Act requires that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not

sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. A hardship exemption to the payment reduction is authorized under section 1834(l)(17)(D)(iii) of the Act, which provides that the Secretary may exempt a ground ambulance provider or supplier from the payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period. Lastly, section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish an informal review process under which a ground ambulance provider or supplier may seek an informal review of a determination that the provider or supplier is subject to the payment reduction.

Section 1834(l)(17)(E)(i) allows the Secretary to revise the data collection system as appropriate and, if available, taking into consideration the report (or reports) that the Medicare Payment Advisory Commission (MedPAC) will submit to Congress. Section 1834(l)(17)(E)(ii) of the Act specifies that, to continue to evaluate the extent to which reported costs relate to payment rates under section 1834(l) of the Act and other purposes as the Secretary deems appropriate, the Secretary shall require ground ambulance providers and suppliers to submit information for years after 2024, but in no case less often than once every 3 years, as determined appropriate by the Secretary.

As required by section 1834(l)(17)(F) of the Act, not later than March 15, 2023, and as determined necessary by MedPAC, MedPAC must assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system, the adequacy of payments for ground ambulance services and geographic variations in the cost of furnishing such services. The report must contain the following:

- An analysis of information submitted through the data collection system;
- An analysis of any burden on ground ambulance providers and suppliers associated with the data collection system;
- A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised by the Secretary, as provided under section 1834(l)(17)(E)(i) of the Act; and
- Other information determined appropriate by MedPAC.

Section 1834(l)(17)(G) of the Act requires the Secretary to post information on the results of the data collection on the CMS website, as determined appropriate by the Secretary.

Section 1834(l)(17)(H) of the Act requires the Secretary to implement the provisions of section 1834(l)(17) of the Act through notice and comment rulemaking.

Section 1834(l)(17)(I) of the Act provides that the Paperwork Reduction Act (Title 44, Chapter 35 of the U.S. Code) does not apply to collection of information required under section 1834(l)(17) of the Act.

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents.

We note that while the requirements of section 1834(l)(17) of the Act are specific to ground ambulance organizations, many stakeholders have expressed interest to us in making this type of information available for other providers and suppliers of ambulance services. For example, air ambulance organizations have suggested they are interested in making this information available. We recognize that the regulation of air ambulances spans multiple federal agencies, and note that section 418 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254, enacted October 5, 2018) requires the Secretary of HHS, in consultation with the Secretary of Transportation, to establish an advisory committee that includes HHS, DOT, and others to review options to improve the disclosure of charges and fees for air medical services, better inform consumers of insurance options for those services, and better inform and protect consumers of these services. We welcome comments on the state of the air ambulance industry and how CMS can work within its statutory authority to ensure that appropriate payments are made to air ambulance organizations serving the Medicare population.

3. Research To Inform the Development of a Ground Ambulance Data Collection System

To inform the development of a ground ambulance data collection system, including a representative sampling plan, our contractor developed recommendations regarding the methodology for collecting cost, revenue, utilization and other information from ground ambulance providers and suppliers (collectively referred to in this proposed rule as ''ground ambulance organizations'') and a sampling plan consistent with sections 1834(l)(17)(A) and (B) of the Act. Our contractor also developed recommendations for the collection and reporting of data with the least amount of burden possible to ground ambulance organizations. The recommendations took into consideration the following:

- An environmental scan consisting of a review of existing peer-reviewed literature, government and association reports, and targeted web searches. The purpose of the environmental scan was to collect information on costs and revenues of ground ambulance transportation services, identify background information regarding the differences among ground ambulance organizations including state and local requirements that may impact the costs of providing ambulance services, and describe financial challenges facing the ambulance industry. Five previously fielded ambulance cost collection tools were also identified and analyzed and are described below.
- Interviews with ambulance providers and suppliers, billing companies, and other stakeholders to determine all major cost, revenue, and utilization components, and differences in these components across ground ambulance organizations. These discussions provided valuable information on the process for developing a data collection system, including how to best elicit valid responses and limit burden on respondents, as well as the timing of the data collection.
- Analyses of Medicare claims and enrollment data, including all fee-for-service (FFS) Medicare claims with dates of service in 2016, the most recent complete year of claims data for ground ambulance services.

Our contractor also analyzed the following five data collection tools that currently collect or have collected data from ground ambulance organizations:

- The Moran Company Statistical and Financial Data Survey (the ''Moran

survey'').[85] In 2012, American Ambulance Association (AAA) commissioned a study with the goal of developing a data collection instrument and making recommendations for collecting data to determine the costs of delivering ground ambulance services to Medicare beneficiaries. The result was the Moran survey, which is a two-step data collection method in which all ambulance providers and suppliers first complete a short survey with basic descriptive information on their characteristics, and second, a representative sample of ambulance providers and suppliers report more specific cost information.

- Ground Emergency Medical Transportation (GEMT) Cost Report form and instructions from California's Medicaid program.[86] The GEMT Cost Report form and instructions is used by some states to determine whether ambulance providers and suppliers should receive supplemental payments from state Medicaid programs to cover shortfalls between revenue and costs. This data collection instrument is geared toward government entities, as private ambulance providers and suppliers do not qualify for the supplemental payments.
- The Emergency Medical Services Cost Analysis Project (EMSCAP) framework.[87] The National Highway Traffic Safety Administration funded EMSCAP in 2007 to develop a framework for determining the cost for an EMS system at the community level. Subsequently, EMSCAP researchers used this framework to develop a cost workbook and pilot test the instrument on three communities representing rural, urban, and suburban areas. EMS services within the three communities included volunteer, paid, and combination EMS agencies, both fire department and third service-based. Third service-based refers to services provided by a local government that include a fire department, police department and a separate EMS, forming an emergency trio.
- A 2012 Government Accountability Office (GAO) ambulance survey.[88] To examine ground ambulance suppliers' costs for transports, in 2012 GAO administered a web-based survey to a random sample of 294 eligible ambulance suppliers. GAO collected data on their 2010 costs, revenues, transports, and organizational characteristics. Although the GAO survey collected data for each domain at the summary level, it also prompted respondents to take into account multiple factors when calculating their summary costs.
- The Rural Ambulance Service Budget Model.[89] This tool was developed by a task force of the Rural EMS and Trauma Technical Assistance Center with funds from the Health Resources and Services Administration (HRSA) in the early 2000s. The purpose was to provide assistance to rural ambulance entities in establishing an annual budget and to calculate the value of services donated by other entities, as well as services donated by the ambulance entity's staff to the community. The tool was last updated in 2010 and has been cited as a resource for rural ground ambulance organizations by state and national government agencies. However, use of the tool is not required by any of these agencies.

Our contractor's analysis of these tools revealed that while there was overlap of the broad cost categories collected (for example, labor, vehicles, and facilities costs) via these tools, there were significant differences in the more specific data collected within these broad categories. Overall, there was a large amount of variability regarding whether the tools allowed for detailed accounting of costs and whether the tools used respondent-defined or survey-defined categories for reporting. The five tools also differed in terms of their instructions, format, and design in terms of how a portion of organizations' total costs were allocated to ground ambulance costs, the time frame for reporting, and the flexibility of reporting.

Based on these activities, our contractor prepared a report entitled, ''Medicare Ground Ambulance Data Collection System—Sampling and Data Collection Instrument Considerations and Recommendations'' (referred to as ''the CAMH[90] report'') which is referenced throughout this proposed rule. It is available at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html* and provides more detail on the research, findings and recommendations concerning the data collection instrument and sampling. This report, in addition to other considerations we describe below, informed our proposals for the data collection instrument.

4. Proposals for the Data Collection Instrument

a. Proposed Format

We considered several options for collecting the data including a survey, a cost report spreadsheet like the GEMT, and the Medicare Cost Report (MCR). During interviews with ambulance providers and suppliers, some participants stated that they would prefer that data collection be done through a cost report spreadsheet, rather than a survey, such as the GEMT and other similar data collection tools utilized by state Medicaid programs. They noted that data cost collection spreadsheets such as the GEMT are used in some states where supplemental payments are made to ground ambulance organizations based on costs and revenue reported via a cost reporting template. Although these tools are valuable to the ambulance suppliers that utilize them for Medicaid payment purposes, we note that only a small number of states make use of these tools for the purpose of providing supplemental payments and that they are generally geared toward government run entities that provide a broad range of emergency medical services and not just ground ambulance services. For these reasons, we do not believe that these tools could be used by all ground ambulance organizations for Medicare payment purposes without significant revision.

Other ambulance providers and suppliers stated their preference for survey-based reporting, such as the Moran survey, because they believe survey reporting is less burdensome and allows more flexibility for reporting. We agree that survey reporting can be designed to provide greater flexibility of reporting with reduced reporting burden. However, the Moran survey recommended excluding small ground ambulance organizations with limited capacity or those which relied heavily

[85] The Moran Company (2014). Detailing ''Hybrid Data Collection Method'' for the Ambulance Industry: Beta Test Results of the Statistical & Financial Data Survey & Recommendations, [Online]. Available at *https://s3.amazonaws.com/americanambulance-advocacy/AAA+Final+Report+Detailing+Hybrid+Data+Collection+Method.pdf.*

[86] State of California—Health and Human Services Agency Department of Health Care Services Ground Emergency Medical Transportation (2013). Ground Emergency Medical Transportation Services Cost Report General Instructions for Completing Cost Report Forms, [Online]. Available at *http://www.dhcs.ca.gov/provgovpart/documents/gemt/gemt_cstrptinstr.pdf.*

[87] Lerner, E.B., Nichol, G., Spaite, D.W., Garrison, H.G., & Maio, R.F. (2007). A comprehensive framework for determining the cost of an emergency medical services system. Available at *https://www.mcw.edu/departments/emergency-medicine/research/emergency-medical-services-cost-analysis-project.*

[88] U.S. Government Accountability Office (2012). Survey of Ambulance Services. Available at *https://www.gao.gov/assets/650/649018.pdf.*

[89] Health Resources and Services Administration. The Rural Ambulance Service Budget Model, [Online]. Available at *https://www.ruralcenter.org/resource-library/rural-ambulance-service-budget-model.*

[90] CMS Alliance to Modernize Healthcare.

on volunteer services, which would exclude a large percentage of ground ambulance organizations from our sample. It would also not take into account the unique differences of government run ground ambulance entities, and specifically ground ambulance entities that provide other emergency services such as fire services, and could not be used by all ground ambulance organizations without significant revisions. Some ambulance organizations that favored using the Moran survey also recommended using cost reporting guidelines that are similar to the CMS requirements for the MCR. Although we agree that standardization is important for data analysis, many smaller ground ambulance organizations have said they would have difficulty complying with complex cost reporting guidelines. We believe that requiring ground ambulance organizations to complete and submit an MCR for the purpose of the data collection required in section 1834(l)(17) of the Act would be unnecessarily resource intensive and burdensome.

We also considered using multiple instruments or staged data collection as recommended in the Moran Report, where we would first collect organizational characteristic data from all ground ambulance organizations, use that information for sampling purposes, and then collect cost and revenue information from a sample of ambulance providers and suppliers. Using this approach, we would need 100 percent participation from all ground ambulance organizations in reporting the organizational characteristic data in order for the data to be used for sampling purposes. We are not proposing this approach because we believe multiple data collections would increase respondent burden and may not align with sections 1834(l)(17)(A) and (B) of the Act which requires CMS to collect data from a random sample and prohibits data collection from the same ground ambulance organizations in 2 consecutive years to the extent practicable. We will discuss this more in the options we considered for sampling section of this proposed rule.

Based on our analysis of the existing or previously used data collection instruments described above, we do not believe that any of them would be sufficient to adequately capture the data required by section 1834(l) of the Act. Therefore, we are proposing to collect ground ambulance organization data using a survey that we developed specifically for this purpose, which we will refer to from this point forward in this proposed rule as the data collection instrument, and which we would make available via a secure web-based system. We believe that the data collection instrument should be usable by all ground ambulance organizations, regardless of their size, scope of operations and services offered, and structure. The proposed data collection instrument includes screening questions and skip patterns that direct ground ambulance organizations to only view and respond to questions that apply to their specific type of organization. We also believe that the proposed data collection instrument is easier to navigate and less time consuming to complete than a cost report spreadsheet. The proposed secure web-based survey would be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS on how to use the system. We are also proposing to codify these policies at § 414.626.

b. Proposed Scope of Cost, Revenue, and Utilization Data

Section 1834(l)(17)(A) of the Act requires CMS to develop a data collection system to collect data related to cost, revenue, utilization, and other information determined appropriate by the Secretary for ground ambulance organizations. Section 1834(1)(17)(A)(i) of the Act further specifies that the information collected through the system should be sufficient to evaluate the extent to which reported costs relate to payment rates.

We considered several options regarding the scope of collecting data on ground ambulance cost, revenue, and utilization. One option would be to require ground ambulance organizations to report on their: (1) Total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. This approach would consider all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary. The advantage of this approach is that ground ambulance organizations already track information at their organizational level on total costs, revenue, and utilization for their own internal budgeting and planning. This method was also used to calculate an organization-level average cost per transport in two previous studies described below:

In a 2012 study entitled, ''Ambulance Providers: Costs and Medicare Margins Varied Widely; Transports of Beneficiaries has Increased'',[91] the GAO performed an analysis to assess how Medicare payments, including the temporary add-on payments, compared to costs reported using a survey. The GAO collected information via a survey on organizations' total costs, including operating and capital costs, without restriction to costs associated with Medicare transports or costs incurred in responding to calls for service from Medicare beneficiaries. GAO then divided reported total costs by the reported number of transports (regardless of whether Medicare paid for the transport) to calculate an average cost per transport for each organization, and reported summary statistics across these averages, including a median cost per transport of $429. However, to simplify data collection and analysis, the analysis was limited to ambulance suppliers that did not share operational costs with a fire department, hospital, or other entity. GAO stated that its calculations assumed that this average cost per transport was constant for all of an organization's transports regardless of whether or not the patient transported was a Medicare beneficiary. This approach implicitly loads the costs associated with activities that did not result in a transport, such as responses by a ground ambulance where the patient could not be located, refused transport, or was treated on the scene, into the estimated cost per transport.

The second study, ''Report to Congress Evaluation of Hospitals' Ambulance Data on Medicare Cost Reports and Feasibility of Obtaining Cost Data from All Ambulance Providers and Suppliers,'' [92] was conducted by HHS as required under the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013). This report used data from Medicare cost reports as its data source, rather than a survey, and included only ambulance providers, rather than ambulance providers and suppliers. It described substantially higher costs per transports for ambulance providers compared to the estimate from GAO, with a median of approximately $1,750 per transport. It did not compare reported total costs to Medicare revenue tallied in claims data with and without the temporary add-on payments. Neither the GAO nor the HHS report compared costs and AFS payment rates for specific Healthcare Common Procedure Coding System

[91] This report is available at *https://www.gao.gov/assets/650/649018.pdf.*

[92] This report is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.*

(HCPCS) codes because the available cost data in both studies did not support that level of analysis.

Another option would be to consider only those costs that are relevant to ground ambulance services furnished to Medicare beneficiaries. Collecting costs associated with specific services (such as Medicare transports) and excluding other services (such as Medicaid transports or responses that did not result in transport) would require either a much more intensive and costly data collection approach (such as time and motion studies) or assumptions on which portions of total costs were related to the specific activity. We believe this approach would be overly burdensome and complex for ground ambulance organizations, especially those who provide other services in addition to ground ambulance services.

A third option would be to consider only those costs that are related to the specific ground ambulance transport services that are paid under the AFS. This would require ground ambulance organizations to report costs, revenue, and utilization related to specific levels of services reported with HCPCS codes, but not costs, revenue, and utilization for other services such as responses that did not result in a transport (which is not covered under the AFS). We believe this option would also be overly burdensome and complex.

In discussions with ambulance providers and suppliers, we were informed that ground ambulance organizations most often track organization-level total costs, revenue, and utilization across all activities and services furnished to all patients, and that most would find it difficult to report costs, revenue, and utilization associated with services furnished exclusively to Medicare beneficiaries or associated with Medicare services covered under the AFS.

Therefore, we propose the first option as discussed above, which would require ground ambulance organizations to report on their: (1) Total costs related to ground ambulance services; (2) total revenue from ground ambulance services; and (3) total ground ambulance service utilization. This approach would consider all ground ambulance costs, revenue, and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary to collect total cost, total revenue, and total utilization data.

Although we are proposing to collect a ground ambulance organization's total costs and total revenues, we are aware that many ground ambulance organizations share operational costs with fire departments, other public service organizations, air ambulance services, hospitals, and other entities. For these organizations, only a portion of certain capital and operational costs contribute to total ground ambulance costs, and only a portion of revenue is from ground ambulance services. We are also aware that some ground ambulance suppliers deploy emergency medical technicians (EMTs) in fire trucks, which would make it difficult to determine whether the fire truck costs should be factored into the total ground ambulance costs, and if so, how that would be calculated.

One option to address these challenges is to limit data collection to ground ambulance organizations that do not share operational costs with fire departments, hospitals, or other entities, as GAO did for their 2012 report. However, we do not believe this approach meets the requirement in section 1834(l)(17)(B)(ii) of the Act for a representative sample because many ambulance suppliers and all ambulance providers share operational costs with fire, police, health care delivery or other activities. We also considered including providers' and suppliers' total costs and revenues across all activities. While this would simplify cost and revenue data reporting, the resulting data would not be limited to ground ambulance activities, and therefore, would result in biased estimates of ground ambulance costs or require significant assumptions to estimate ground ambulance costs alone.

To more accurately define total costs and total revenues related to ground ambulance services for those ground ambulance organizations that provide other services in addition to ground ambulance services, we are proposing an approach where the data collection instrument instructions would separately address three further refined proposed categories of total ground ambulance costs and revenues:

- *Cost and revenue components completely unrelated to ground ambulance services.* These costs and revenues would be unrelated to this data collection and not reported. Examples include administrative staff without ground ambulance responsibilities, health care delivery outside of ground ambulance, community paramedicine, community education and outreach, and fire and police public safety response.
- *Cost and revenue components partially related to ground ambulance services.* These costs and revenue would be reported in full, but respondents would report additional information that can be used to allocate a portion of the costs to ground ambulance services. Depending on how the data would be utilized, certain costs could be included or excluded from an analysis after data are collected. Examples include EMTs who are also firefighters and facilities with both ground ambulance and fire department functions. (We considered an alternative where respondents would allocate costs and report only costs associated with ground ambulance services but believe that would pose an additional burden on the respondent to calculate allocated amounts, and would result in an allocation process that is less transparent and standardized).
- *Cost and revenue components entirely related to ground ambulance services.* These costs are reported in full. Examples include EMTs with only ground ambulance responsibilities and ground ambulance vehicles.

We believe that this approach would enable us to collect the data necessary to evaluate the adequacy of payments for ground ambulance services, the utilization of capital equipment and ambulance capacity, and the geographic variation in the cost of furnishing such services. The data could be analyzed in the same manner as the data in the GAO report, for example, calculating an average per-transport cost for each organization and calculating Medicare margins with and without add-on payments, or could provide the basis for other analyses to link reported costs to AFS rates. For example, an analysis could use reported total costs and information on the volume of transports by levels of services to estimate a cost for each HCPCS code reported for the AFS, or regression-based approaches to estimate the marginal cost of furnishing each HCPCS code on the AFS. We believe that under our proposed approach, the collected data would be available to estimate total costs and revenue relevant to ground ambulance services.

c. Proposed Data Collection Elements

The draft data collection instrument is available on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.* An overview of the elements of the data collection instrument we are proposing is in Table 29, including information on costs, revenues, utilization (which we define for the purposes of the instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations.

To help structure the data collection instrument, we organized costs by category (for example, labor, vehicles, and facilities), which is the approach

used in the GEMT and the AAA/Moran survey.

TABLE 29—PROPOSED COMPONENTS FOR THE DATA COLLECTION INSTRUMENT

Component (data collection instrument section)	Broad description
Ground ambulance organization characteristics (2–4).	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground ambulance service volume and service mix (5 and 6).	Number of responses and transports, level of services reported by HCPCS code.
Costs (7–12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Number and costs associated with EMTs administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; rent and mortgage payments, insurance, maintenance, and utility costs.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual depreciation; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

The following sections describe our proposed approach for data collection in each of these categories.

(1) Collecting Data on Ground Ambulance Provider and Supplier Characteristics

CMS is required to collect information regarding the geographic location of ground ambulance organizations to meet the requirement at section 1834(l)(17)(A)(iii) of the Act that the collected data include information on services furnished in different geographic locations, including rural areas and low population density areas. We also recognize that there are differences between and among ground ambulance organizations on several key characteristics, including geographic location; ownership (for-profit or non-profit, government or non-government, etc.); service volume, organization type (including whether costs are shared with fire or police response or health care delivery operations); EMS responsibilities; and staffing models. Research conducted for this proposal indicates that:

- There are differences in costs per transport by ground ambulance organizations with a different ownership status;
- EMS level of service and staffing models often have an important impact on costs, with higher EMS levels of service (for example, quicker response times) and static staffing models (that is, mainatining a constant response capability 24 hours a day, 7 days a week, 365 days a year) involving higher fixed costs; and
- Utilization varies significantly across ambulance providers and suppliers of different characteristics.

Due to this variation in characteristics and the effect it has on costs and revenues, we believe it is important for ground ambulance organizations to report additional characterictics, as described below, to adequately analyze the differences in costs and revenue among different types of ambulance providers and suppliers. We also believe collecting this information directly through the proposed data collection instrument will improve data quality with minimal burden on the respondents because the proposed data collection instrument is designed to tailor later sections and questions based on respondents' characteristics through programmed ''skip patterns''. We considered relying exclusively on the Medicare enrollment form CMS 855A for ground ambulance providers or CMS 855B for ground ambulance suppliers to capture this information, but believe that data accuracy would be more robust if reported directly by respondents for the specific purpose of this data collection.

The proposed data collection questions related to organizational characteristics and service area are in sections 2, 3, and 4 of the data collection instrument. We are proposing to collect information on ownership and organization type through a sequence of questions in section 2 of the data collection instrument. Some of the questions in this section are adapted in part from prior surveys (such as the GAO and Moran surveys) with changes as necessary to fit scenarios reported during interviews with ground ambulance organizations. The first question related to organizational characteristics, question 6, asks about the organizations' ownership status. This item aligns closely with a similar question on the Medicare enrollment form CMS 855B for ambulance suppliers. Question 7 asks whether the respondent's organization uses any volunteer labor. While this question could have been asked later in the data collection instrument around the collection of labor data, we opted to include it here because many ground ambulance organizations informed CMS that they view the use of volunteer labor as a defining organizational characteristic, on par with ownership status, and that a volunteer labor question was expected by respondents at this early point in the data collection instrument. Question 8 asks respondents to select a category that best describes their ambulance organization. The response options for this item are mutually exclusive and align with the ambulance provider and supplier taxonomy described in the CAMH report. The next two questions, 9 and 10, more directly ask whether the respondent has shared operational costs with an entity of another type, including a fire department, hospital, or other entity. We are proposing these questions in addition to the organization type question to account for situations where a respondent might primarily identify as an organization of one type (with implications for shared operational costs) but then might have shared

operational costs with another entity type. Responses to questions 9 and 10 play an important role in skip logic later in the data collection instrument regarding questions and response options relevant only to ground ambulance organizations with shared operational costs with an entity of another type.

Other proposed questions regarding organizational characteristics are necessary to tailor later parts of the data collection instrument to the respondent. These include proposed questions in section 2 of the data collection instrument on whether the respondent's ambulance organization:

- Is part of a broader corporation or other entity billing under multiple National Provider Identifiers (NPIs) (question 2).
- Routinely responds to emergency calls for service (question 11).
- Operates land, water, and air ambulances (questions 12–14).
- Has a staffing model that is static (that is, consistent staffing over the course of a day/week) or dynamic (that is, staffing varies over the course of a day/week) or combined deployment (certain times of the day have a fixed number of units, and other times are dynamic depending on need) (question 15).
- Provides continuous (also known as ''24/7/365'') emergency services) (question 16).
- Provides paramedic or other emergency response staff to meet ambulances from other organizations in the course of a response (questions 17 and 18).

In our interviews with ambulance providers and suppliers, some participants indicated that their staffing model is an organizational characteristic that would likely be associated with costs per transport. Organizations that need to maintain fixed staffing levels over time (for example, to maintain an emergency response capability to serve a community) would likely have higher costs than those that do not.

Section 1834(l)(17)(A)(iii) of the Act requires collecting data from ambulance providers and suppliers in different geographic locations, including rural areas and low population density areas. The area served by ambulance providers and suppliers is an important characteristic and we are proposing to collect information on the geographic area served by each ambulance provider and supplier in section 3 of the data collection instrument.

Many ground ambulance organizations have a primary service area in which they are responsible for a certain type of service (for example, ALS–1 emergency response within the borders of a county, town, or other municipality) and may have secondary services areas for a variety reasons, such as providing mutual or auto aid, or providing a different service in a secondary area (for example, non-emergency transports state-wide). We considered several alternatives to collect information on service area. One option would be to utilize Medicare claims data, but this would limit the information to Medicare billed transports only and would also not differentiate between primary and other service areas. Another option would be to allow respondents to write in a description of their primary and other service areas, but this would require converting written responses to a format that can be used for analysis. A third option would be for respondents to report the ZIP codes that constitute their primary and other service area. This approach aligns with the Medicare enrollment process requirement to submit ZIP codes where the ground ambulance organization operates. It would also collect ZIP code-based information on service area that can be easily linked to the ZIP Code to Carrier Locality file [93] that lists each ZIP code and its designation as urban; rural; or super-rural. This file is used by the MACs to determine if the temporary add-on payments should apply to a transport under the AFS. The main limitation of this approach is that ZIP codes would not always align to service areas, because ZIP codes routinely cross town, county, and other boundaries that are likely relevant for defining ground ambulance organizations' service areas.

We are proposing to require ground ambulance organizations that are selected during sampling to identify their primary service area by either: (1) Providing a list of ZIP codes that constitute their primary service area; or (2) selecting a primary service area using pre-populated drop-down menus at the county and municipality level in question 1, section 3 of the data collection instrument. We are also proposing to require respondents to specify whether they have a ''secondary'' service area, which are areas where services are regularly provided under mutual aid, auto-aid, or other agreements in section 3, question 4 of the data collection instrument and if so, to identify the secondary service area using ZIP codes or other regions as described above for the primary service area (section 3, question 5). Mutual aid agreements are joint agreements with neighboring areas in which they can ask each other for assistance. Auto-aid arrangements allow a central dispatch to send the closest ambulance to the scene. We are not proposing to collect information on areas served only in exceptional circumstances, such as areas rarely served under mutual or auto-aid agreements or deployments in response to natural disasters or mass casualty events because we believe reporting on rarely-served areas would involve significant additional burden and would add to instrument complexity without generating data that would be useful for analysis.

The proposed approach distinguishes between primary and secondary service areas. This would allow subsequent questions on the balance of transports in a respondent's primary versus secondary service area and whether average trip time and response times are substantively longer in the secondary versus primary service area. We believe this approach results in data that can be easily analyzed and eliminates the need to ask certain other questions (such as the population and square mileage of the respondent's service area) because this information can be inferred using the reported geographic service area boundaries.

We are proposing to ask the following questions in sections 3 and 4 of the of the data collection instrument, service area and subsequent emergency response time, because the responses to these questions are closely related to the area served by the organization:

- Whether the respondent is the primary emergency ambulance organization for at least one type of service in their primary service area (section 3, question 2).
- Average trip time in primary and secondary service areas (section 3, questions 3 and 6).
- Average response time (for organizations responding to emergency calls for service) for primary and secondary service areas (section 4, questions 1–2).
- Whether the organization is required or incentivized to meet response time targets by contract or other arrangement (for organizations responding to emergency calls for service) (section 4, question 3).

Average trip and response time are necessary to understand how geographic distance between the ground ambulance organization's facilities and patients affects costs. In interviews, ground ambulance organizations recommended the collection of average trip time in addition to mileage because some rural and remote areas may have relatively

[93] Available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html.*

long average trip times even though mileage may be more modest due to terrain, the quality of roads, and other factors. We believe that collecting information on average response time would allow the analysis of whether communities with different response time expectations and targets have systematically different costs.

(2) Collecting Data on Ground Ambulance Utilization

CMS is required to collect information on the utilization of ground ambulance services. While we could collect information on the volume of ground ambulance services that can be billed to Medicare, this approach would not provide information needed to determine total utilization of ground ambulance organizations. Another option would be to utilize Medicare claims data for estimates of ground ambulance transport volume and separately collect information on services not payable by Medicare (such as responses that did not result in a transport). This approach would also not provide complete information on total transport volume, since other services, such as responses that do not result in a transport, would not be included.

Based on information provided during interviews with ground ambulance organizations, we identified several distinct utilization categories, such as total responses and ground ambulance responses. This is particularly important for fire-based and police-based organizations that may have a significant volume of fire and police responses that do not involve a ground ambulance. The number of responses that did not result in a transport can be separately tallied. Other important utilization categories are ground ambulance transports (that is, responses during which a patient is loaded in a ground ambulance), which can be measured in terms of total transports (that is, all ground ambulance transports regardless of payor) or paid transports (that is, transports for which the ambulance provider or supplier was paid in part or in full). Another utilization category would include information on ambulance providers and suppliers that furnish paramedic intercept services or provide paramedic-level staff in the course of a BLS response where another organization provides the ground ambulance transport.

We believe it is important to collect utilization data related to all services, not just transports, because other services that contribute to the total volume of responses have direct implications for costs. Collecting utilization information related to transports but not other services could omit important cost information. Some utilization measures, such as the ratio of ground ambulance to total responses, may be one basis for allocating certain costs reported elsewhere in the data collection instrument. Another example would be the difference between total and paid transport, as this would provide information on services that were provided to patients but for which no payment is received.

To best capture the full range of utilization data, we are proposing a two-pronged approach to collect data on the volume and the mix of services. First, we are proposing to collect total volume of services for each of the categories listed below in section 5 of the proposed data collection instrument:

- Total responses, including those where a ground ambulance was not deployed (question 1).
- Ground ambulance responses, that is, responses where a ground ambulance was deployed (question 2).
- Ground ambulance responses that did not result in a transport (question 4).
- Ground ambulance transports (question 5).
- Paid ground ambulance transports, that is, ground ambulance transports where the ambulance provider or supplier was paid for a billed amount in part or in full (question 6).
- Standby events (question 7).
- Paramedic intercept services as defined by Medicare (question 8).
- Other situations where paramedic staff contributes to a response where another organization provides the ground ambulance transport (question 9).

The CAMH report describes several cases where an ambulance provider or suppliers' mix of services within one of the utilization categories described above could affect costs or revenue. Most importantly, within billed transports, variation in the mix of specific ground ambulance services (for example, ALS versus BLS services) will affect both costs (because ALS transports require more and more costly inputs) and revenue (because ALS services are generally paid at a higher rate). Ground ambulance organizations with a higher share of responses that are emergency responses may also face higher fixed costs, and that the costs for organizations furnishing larger shares of water ambulance transports are likely different than costs from organizations that do not furnish water ambulance transports. There is a subset of ground ambulance organizations that specialize in non-emergency transports or inter-facility transports, which suggests that this business model may result in different per-transport costs compared to EMS-focused ambulance providers and suppliers.

Second, to account for this significant variation, we are proposing to collect the following information related to service mix:

- The share of responses that were emergency versus non-emergency (section 6 question 1).
- The share of transports that were land versus water (asked only of organizations reporting that they operate water ambulances; section 6 question 2).
- The share of transports by service level (section 6 question 3).
- The share of transports that were inter-facility transports (section 6 question 4).

We are not proposing that respondents report on their mix of services in primary and secondary service areas (as defined above) separately because this would double the length of this section of the data collection instrument and require complex calculations or use of assumptions by respondents that do not separately track services by area. Instead, we are proposing that respondents report the share of total ground ambulance responses that were in a secondary rather than primary service area in a single item (section 5 question 3). We also are not proposing to collect detailed information regarding the mix of services for total transports (versus paid transports) and paid transports (versus total transports) because collecting information on the mix of services for total and paid transports separately would double the reporting burden in this section and because we believe, based on discussions with stakeholders, that it is reasonable to assume that the distribution of transports across categories would be the same.

(3) Collecting Data on Costs

Section 1834(l)(17)(A) of the Act requires CMS to collect cost information from ground ambulance organizations, and we previously discussed our proposal to collect data on a ground ambulance organization's total costs. This part of the proposed rule describes the data in each cost category that we are proposing to collect, as well as alternatives that we considered.

The costs reported separately in the categories of costs we are proposing to collect would sum to an organization's total ground ambulance costs. In addition to ground ambulance costs, we are proposing to ask all respondents in the proposed data collection instrument

to report their total annual costs (that is, operating and capital expenses), inclusive of costs unrelated to ground ambulance services, in a single survey item (section 12, question 1). For ground ambulance organizations that do not have costs from other activities (such as from operating a fire or police department), the reported total costs are a way to cross-check costs reported in individual cost categories throughout the instrument, and we can compare the reported total to the sum of costs across categories. Such a cross-check may also be appropriate for ground ambulance organizations with costs from other activities, as the sum of costs across ground ambulance cost categories should always be less than the ground ambulance organization's reported total costs. We believe that this cross-check will improve data quality and is consistent with existing survey-based data collection tools. This approach will also provide a better understanding of the overall size and scope of ground ambulance organizations, including activities other than providing ground ambulance services. Relatively larger organizations may have lower ground ambulance costs due to due to economies of scale and scope.

To avoid reporting the same costs multiple times, there are instructions and reminders throughout the proposed data collection instrument to avoid double-counting of costs. From a design perspective, we believe it is less important where a particular cost is reported on the survey data collection instrument and more important that the cost is reported only once.

We are making two proposals that have important implications for reporting in all cost sections in the proposed data collection instrument. First, in the case where a sampled organization is part of a broader organization (such as when a single parent company operates different ground ambulance suppliers), we propose to ask the respondents to report an allocated portion of the relevant ground ambulance labor, facilities, vehicle, supply/equipment, and other costs from the broader parent organization level in separate questions in several places in the cost sections of the data collection instrument (section 7.2 question 3, section 8.2 question 2, section 8.3 question 2, section 9.2 question 5, section 9.3 question 6, section 10.2 question 4, and section 11 questions 2 and 5). This scenario is discussed in more detail in the sampling section below. In exploratory analyses, we found that a small share of NPIs were part of broader parent organizations. Due to the rarity of this scenario and the complexity of calculations required, we are proposing to allow the respondent to report an allocated amount directly for these questions using an allocation approach they regularly use for this purpose. We believe that while proposing a specific allocation approach would yield more uniform and transparent data, we believe that these benefits are not worth the additional respondent burden.

Second, we are proposing to include a general instruction stating that in cases where costs are paid by another entity with which the respondent has an ongoing business relationship, the respondent must collect and report these costs to ensure that the data reported reflects all costs relevant to ground ambulance services. Examples include when a municipality pays rent, utilities, or benefits directly for a government or non-profit ambulance organization, or when hospitals provide supplies and/or medications to ground ambulance operations at no cost. During interviews with ground ambulance organizations, we were told that there are many nuanced arrangements that fit this broad scenario. Although we recognize this would be an additional step for some ground ambulance organizations, we are concerned that the lack of reported cost data in one of these major categories could significantly affect calculated total cost.

Because some ambulances, other vehicles, and buildings are donated to ground ambulance organizations, we considered asking respondents to report fair market values for these vehicles and buildings. However, we are aware that while the lack of reported cost data in one of these major categories could affect calculated total cost, it is not always clear what cost is appropriate to report. To avoid the subjectivity and burden involved in asking respondents to report fair market value, we propose instead that respondents report which ambulances, other vehicles, and buildings have been donated, but not an estimate of the fair market value of those donations. We believe fair market values could be imputed using publicly available sources of data to facilitate comparison of data between organizations that have donations and those that do not. For the same reasons, we are also proposing not to collect an estimate of fair market value for donated equipment, supplies, and costs collected in the ''other costs'' section of the instrument. As noted above, for those organizations with costs that were paid by another entity with which the respondent has an ongoing business relationship, such as a ground ambulance organization that is part of or owned by a government entity, respondents would obtain the cost information directly from that entity since we would not consider these to be donated items.

The following sections describe each cost category, alternative for data collection, and our proposals related to each category of costs separately.

(i.) Collecting Data on Staffing and Labor Costs

In interviews with ambulance providers and suppliers, they stated that labor is one the largest contributors to total ground ambulance costs (especially medical staff such as EMTs, paramedics, and medical directors) and that they use a broad mix of labor types and hiring arrangements. There is also significant variation in tracking staffing and labor cost inputs that are needed to calculate costs. We were also informed by ambulance providers and suppliers that data on the number of ground ambulance staff and associated labor costs were often available at one of three levels: The individual employee level; aggregated by category such as EMT-Basic or Medical Director; or aggregated across all staff. Additionally, we were told by ambulance providers and suppliers that ground ambulance organizations typically face challenges in tracking ground ambulance staff and costs by category when staff had multiple ground ambulance responsibilities (for example, EMTs with supervisory responsibilities, EMTs who are also firefighters, etc.).

We agree that labor costs are an important component of total costs and believe that it is necessary to collect information on both staffing levels, that is, the quantity of labor used, and the labor costs resulting from these labor inputs. Without information on staffing levels, we would not be able to gauge whether differences in labor costs are due to compensation or different levels of staffing. Collecting information on staffing levels also allows the use of imputed labor rates from other sources (such as the Bureau of Labor Statistics). We also acknowledge the practical need to balance the burden involved in reporting extremely detailed staffing and labor costs information against the usefulness of detailed data for explaining variation in ground ambulance costs. Therefore, we are proposing to collect information in the proposed data collection instrument on the number of staff and labor costs for several detailed categories of response staff (for example, EMT-basic, EMT-intermediate, and EMT-paramedic) (section 7.1), and for a single category for paid administrative and facilities

staff (for example, executives, billing staff, and maintenance staff) (section 7.2), and (c) separately for medical directors (section 7.2). We believe this approach involves less respondent burden compared to reporting on each individual staff member. If more detailed categories were used for reporting staffing levels and costs, we believe the burden involved in assigning paid administrative and facilities staff with multiple roles to individual categories or apportioning their labor and costs to separate categories would increase.

The main limitation of the proposed approach is that we would not collect detailed information on specific paid administration and facilities labor categories. Therefore, we are also proposing to collect some information that would help explain variation in labor costs by asking whether the ground ambulance organization has some staff in more specific paid administration and facilities categories such as billing, dispatch, and maintenance staff (section 7, question 1). This question also serves as a screening question to determine which response options appear to the respondent in several other questions in this section of the proposed data collection instrument. We also propose to ask for information on why individual labor categories are not used (section 7, question 1) and if there is at least one individual with 20 hours a week or more of effort devoted to specific activities such as training and quality assurance (section 7.2, question 2).

Reporting Staffing Levels

In reporting staffing levels in the proposed data collection instrument, we considered several approaches. One approach we considered was asking the respondent to report only the number of staff (that is, counts of people). Under this approach, a part-time employee would count as ''1'' to the number of staff even if they worked a small number of hours per week. We believe this approach would result in less accurate reporting of labor inputs, especially from organizations relying heavily on part-time staff or staff with responsibilities unrelated to ground ambulance services. We also considered allowing respondents to report full-time-equivalent (FTE) staff on a 40-hour per week basis, but ground ambulance organizations informed us that reporting FTEs would be burdensome. As a third approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours over a reporting year. Reporting labor hours over the entire reporting year allows for more accurate reporting of staff working part-time and may involve less burden for respondents that already tally annual labor hours (for example, via payroll records), but would likely be difficult for those who do not already track labor hours in this manner. As a fourth approach, we considered asking respondents to report ground ambulance staffing levels in terms of hours worked during a typical week. Reporting staffing levels in terms of hours worked either over a reporting year or during a typical week allows detailed accounting of part-time staff and staff with ground ambulance and other responsibilities and involves fewer calculations and adjustments than reporting FTEs. Reporting in terms of hours over a typical week has the additional advantage of simplifying reporting for staff that start or stop work during the 12-month reporting period. The main limitation of reporting staffing levels in terms of hours over a typical week is that the week that the respondent selects for reporting may not be generalizable to other weeks in the reporting period.

In the interest of minimizing reporting burden, we are proposing to collect information on the number of staff in terms of hours worked over a typical week (sections 7.1 and 7.2). The instructions in the proposed data collection instrument ask respondents to ''select a week for reporting that is typical, in terms of seasonality, in the volume of services that you offer (if any) and staffing levels during the reporting year.''

Scope of Reported Labor Costs

For the purposes of collecting information on labor costs, we are proposing to define labor costs to include compensation, benefits (for example, healthcare, paid time off, retirement contributions, etc.), stipends, overtime pay, and all other compensation to staff. We refer to these costs as fully-burdened costs. Some ambulance providers and suppliers track compensation but not benefits because another entity, such as a municipality, pays for benefits, and that the ability of these ambulance providers and suppliers to report fully burdened costs may be limited. Despite this limitation, due to the importance of labor costs as a component of total ground ambulance costs, we believe that information on fully burdened costs (sections 7.1 and 7.2) must be reported so that all relevant ground ambulance transport costs are collected. Ambulance providers and suppliers selected to report data may need to implement new tracking systems or request information from other entities (such as municipalities) to be able to report fully-burdened labor costs.

Volunteer Labor

Ground ambulance organizations have also informed CMS that a significant share of ambulance providers and suppliers rely in part or entirely on volunteer labor and that the systems and data available to track the number of volunteers and the time that they devote to ground ambulance services varies. We are proposing to collect information on the total number of volunteers and the total volunteer hours in a typical week using the same EMT/response staff and administrative and facilities staff categories used elsewhere in the proposed data collection instrument (section 7.3, questions 1–5). Although some suggested that assigning a value to volunteer labor hours may be important, the proposed data collection instrument collects information only on the amount of volunteer labor (measured in hours in a typical week) and not a market value for that labor. We believe reported hours can be converted, if necessary, to market rates using data from other sources. We are also proposing to collect the total realized costs associated with volunteer labor such as stipends, honorariums, and other benefits to ensure all costs associated with ground ambulance transport are collected (section 7.3, question 6).

Allocation and Reporting Staff With Other Non-Ground Ambulance Responsibilities

Since firefighter/EMTs are common in many ambulance suppliers, we are proposing to ask respondents that share costs with a fire or police department to report total hours in a typical week for paid EMT/response staff with fire/police duties only (section 7.1). We believe this information can be used to subtract a portion of associated labor costs when calculating ground ambulance labor costs. We believe our proposed approach is more consistent and involves less burden than asking respondents to perform their own allocation calculations necessary to report only the hours or full-time equivalents related to ground ambulance services.

As already noted, many ground ambulance organizations have staff with responsibilities beyond ground ambulance and fire/police response. To account for these scenarios, we are proposing to ask respondents to report the total hours in a typical week unrelated to ground ambulance or fire/police response duties (which are

addressed separately as described in section 7.1), as the costs associated with this labor can be subtracted by those analyzing the data when calculating ground ambulance labor costs. We believe this proposed approach provides both transparency and consistency in the data with minimal burden, and may avoid scenarios where all of the costs associated with staff with limited ground ambulance responsibilities contribute to total ground ambulance costs.

(ii.) Collecting Data on Facility Costs

Facility costs may include rent, mortgage payments, depreciation, property taxes, utilities, insurance, and maintenance, and the associated costs vary widely across ambulance providers and suppliers. Some ground ambulance organizations own facilities while for others, rent, mortgage, or leasing is an important component of total operational costs. Some ground ambulance organizations share facilities with other operations (such as fire and rescue services), and individual ground ambulance organizations often operate out of several facilities of different types, sizes, and share of space related to ground ambulance operations.

We considered proposing to require respondents to report facilities costs aggregated across all facilities. We believe this approach would minimize burden on the respondent by eliminating the need to break costs down by facility; however, it may also increase the risk for inconsistencies in how respondents report total facilities costs. Under this approach, respondents whose ground ambulance organizations share operational costs with a fire department or other entity would need to calculate and report an estimate of facilities costs that was relevant only to ground ambulance services.

We also considered proposing to require respondents to report all costs on a per-facility basis. We believe this approach would allow the most flexibility in reporting complex facility arrangements from ground ambulance organizations operating out of multiple facilities. However, this approach may also involve more burden, particularly for larger organizations, to report costs on a facility-by-facility basis, and many organizations do not track costs such as maintenance or utilities on a per-facility basis.

We are proposing a hybrid approach involving both per-facility and aggregate reporting of different information. First, respondents report the total number of facilities (section 8., questions 1–2) and then indicate for each facility whether they paid rent, mortgage, or neither during the reporting period, total square footage, and share of square footage related to ground ambulance services (section 8.1, question 3). Second, respondents report their per-facility rent, mortgage, or annual depreciation (section 8.2). Third, respondents report facilities-related insurance, maintenance, utilities, and property taxes aggregated across all facilities (section 8.3).

We believe this proposed approach allows for the collection of the information needed to calculate a total facilities cost related to ground ambulance services while avoiding a burden on respondents to calculate allocated facility costs. Total insurance, maintenance, utility, and property tax costs can be allocated using reported square footage and shares of square footage related to ground ambulance services. The proposed approach requires respondents to provide both the square footage of each facility, and the share of square footage for the facility that is related to ground ambulance operations. We expect that some ground ambulance organizations would have this information available and others would need to collect this square footage information to report along with facilities costs, but do not believe this information would be difficult to collect.

(iii.) Collecting Data on Vehicle Costs

Section 1834(l)(17)(A)(ii) of the Act requires CMS to collect information on ''the utilization of capital equipment and ambulance capacity.'' We are proposing to collect information on the number of ground ambulances and other vehicles related to providing ground ambulance services, as well as the costs associated with these vehicles to meet these requirements.

Ambulance providers and suppliers operate ground ambulances, as well as other vehicles to support their ground ambulance operation, and some may have a variety of other vehicles that are associated with ground ambulance responses. For example, a fire truck staffed with fire personnel cross-trained as EMTs may respond with a ground ambulance to an emergency call. Other vehicles might be used in responses and may be referred to as a non-transporting EMS vehicle, a quick response vehicle, a fly-car, or an SUV that carries a paramedic to meet a BLS ambulance from another organization during the course of a response.

We considered two alternatives for collecting vehicle costs. One alternative would be to only include the costs for ambulances and exclude other certain non-ambulance response vehicles from reported costs. We believe that excluding other certain non-ambulance response vehicles from reported costs could potentially result in underreporting of total ground ambulance costs, particularly among those providers or suppliers that rely heavily on these vehicles to support their ground ambulance services. Another alternative would be to include the costs of all vehicles that are used as part of ambulance services, such as quick response vehicles that are used to supplement ambulances.

For all vehicles, vehicle costs can be reported either in aggregate or on a per-vehicle basis. We believe that while reporting vehicle costs in aggregate may involve less burden for some respondents, those respondents that do not track aggregated costs would still require a tool to enter information on per-vehicle basis. Furthermore, we believe that aggregated costs for vehicles other than ground ambulances offer analysts with fewer alternatives to allocate a share of vehicle costs to ground ambulance services.

We are proposing to collect data on vehicle costs in the proposed data collection instrument in two parts: Ground ambulance vehicles (section 9.1); and all other vehicles related to ground ambulance operations (section 9.2). For ground ambulance vehicles, we are proposing to collect information on the number of vehicles, total miles traveled, and per-vehicle information on annual depreciated value (and remounting costs if applicable) for owned vehicles, and annual lease payments for rented vehicles (section 9.1, questions 1–4). We considered proposing to collect the necessary information to calculate annual depreciated value using a standardized approach. However, we are proposing to allow respondents with owned vehicles to use their own accounting approach to calculate annual depreciated value per vehicle. We believe that allowing flexibility for respondents to use their standard approach for this calculation would result in more accurate data and less reporting burden.

We are also proposing to use a similar approach to collect per-vehicle information for owned and leased vehicles of any other type that contribute to ground ambulance operations, including fire trucks, quick response vehicles, all-terrain vehicles, etc. (section 9.2, questions 1–5). The proposed instructions in section 9.2 of the data collection instrument specify that reported vehicles must support ground ambulance services. We are proposing to collect the type of each vehicle in broad categories in addition

to the annual depreciated value or lease payment amount for each vehicle.

In addition to the above costs, we also are proposing to collect aggregate costs associated with licensing, registration, maintenance, fuel, insurance costs for all vehicles combined (ambulance and non-ambulance) (section 9.3, questions 1–5). We believe that these costs are often aggregated within providers' and suppliers' records and that reporting in aggregate form may reduce respondent burden with minimum risk for reporting error.

When estimating total ground ambulance vehicle costs for ground ambulance organizations that share operational costs with fire and police response or other non-ground ambulance activities, a share of vehicle costs reported via the instrument will need to be allocated as vehicle costs related to ground ambulance services. One alternative we considered to do this was simply to ask respondents about the share of costs associated with ground ambulance services as we thought this would be the least burdensome approach; however, we believe data collected in this manner would not allow for estimation of costs associated with non-ground ambulance vehicles that support ambulance services. We considered another alternative where (1) the ratio of ground ambulance to total responses would be used to allocate costs associated with non-ambulance vehicles, (2) the total number of vehicles would be used to allocate aggregate costs associated with licensing, registration, maintenance, and fuel costs, and (3) depreciated annual costs and/or lease payment amounts would be used to allocate insurance costs. The main limitation of this approach is that maintenance and fuel costs could vary significantly across vehicle categories. For example, maintenance and fuel costs may be significantly different for ground ambulance than for other types of vehicles. As a result, we are proposing a modification of this alternative where we also ask respondents to list percent of total maintenance and fuel costs attributable to each type of vehicle (that is, ground ambulances, fire trucks, land rescue vehicles, water rescue vehicle, other vehicles that respond to emergencies such as quick response vehicles, and other vehicles; section 9.3, questions 4 and 5). We propose to also ask respondents to report total mileage for ground ambulance (land and water separately) and total mileage for other vehicles related to ground ambulance responses (land and water separately) as a potential alternative means to allocate fuel and maintenance costs.

(iv.) Collecting Data on Equipment and Supply Costs

In our interviews with ground ambulance organizations, we were told that not all ground ambulance organizations would be able to report detailed item-by-item equipment and supply information, and that some organizations have far more sophisticated inventory tracking systems than others that would allow them to report detailed information within a category.

We considered alternative approaches related to reporting equipment and supply costs that varied primarily on the level of detail for reporting. We considered extremely detailed data reporting as it would be potentially useful to identify variability in costs across organizations. However, as noted above, many ground ambulance organizations may not keep detailed records of all their individual equipment and supply costs. Taking those factors into account, we are proposing to request total costs in a small number of equipment and supply categories rather than itemized information for all equipment and supply categories (section 10). These would include:

- Capital medical equipment.
- Medications.
- All other medical equipment, supplies, and consumables.
- Capital non-medical equipment.
- Uniforms.
- All other non-medical equipment and supplies.

We also considered whether to have respondents report both medical and non-medical equipment and supplies together. We believe that the majority of medical supplies are more likely to be related to ground ambulance services than non-medical supplies for organizations with shared services, and therefore, we are proposing to collect this information separately.

Reporting of Capital Versus Non-Capital Equipment

To meet the requirement in section 1834(l)(17)(A)(ii) of the Act to collect information to facilitate the analysis of ''the utilization of capital equipment,'' we are proposing to separately collect information on capital equipment expenses (rather than equipment-related operating expenses). Capital equipment (both medical and non-medical) yield utility over time, which can vary depending on the expected service life of the specific good. In addition to the cost of purchasing or leasing durable goods equipment, depreciation and maintenance costs must be considered in the total cost calculations. Since ground ambulance organizations often track capital equipment on an itemized level, separating items of significantly different age and cost is necessary to calculate depreciation. Therefore, to minimize burden by aligning reporting with the accounting approaches used by respondents, we are proposing to ask for capital (section 10.1, question 1; section 10.2, question 1) and non-capital costs (section 10.1, questions 2–3; section 10.2, questions 2–3) separately so that respondents can report annual depreciated costs for capital equipment and total annual costs otherwise. We also are proposing to allow respondents to report annual maintenance and service costs for capital equipment because ground ambulance organizations have stated during interviews that these costs can be significant compared to purchase costs or annual depreciated costs. Finally, we are proposing to allow respondents to use their own standard accounting practice to categorize equipment as capital or non-capital. While we believe it would be possible to ask respondents to use a standard approach, we believe this would require respondents with another practice to recalculate annual depreciated cost and potentially increase respondent burden and reporting errors.

Allocation of Shared Costs

During interviews with ground ambulance organizations, it was noted that although the vast majority of equipment and supplies are for ground ambulance services, some costs are shared with hospitals or clinics. We believe separate reporting on medical and non-medical equipment and supplies would facilitate allocation (section 10.1, versus section 10.2). For organizations that indicate the use of shared services, we are proposing to ask separately what share of medical and non-medical equipment and supply costs are related to ground ambulance services (section 10.1, questions 1c, 2a; section 10.2, questions 1c, 2a, 3a). The share of non-medical equipment and supplies used for ambulance services may vary for respondents with operations beyond ambulance services. While other allocation methods (such as the share of responses that are ground ambulance responses) may be appropriate to allocate equipment and supply costs, asking respondents to provide their estimate of the share of equipment and supply costs related to ambulance services reduces assumptions made about how best to apply allocation across the various equipment and supplies reported.

(v.) Collecting Data on Other Costs

In addition to core costs for ambulance providers and suppliers that are associated with labor, vehicles, facilities, and equipment or supplies, ground ambulance organizations have indicated that these entities incur costs associated with contracted services (for example, for billing, vehicle maintenance, accounting, dispatch or call center services, facilities maintenance, and IT support), as well as other miscellaneous costs (for example, administrative expenses, fees and taxes) to support ground ambulance services.

We considered including contracted services as part of the labor section, since many of the contracted services related to costs that would otherwise be labor-related if the tasks were performed by employed staff. However, we were concerned that ground ambulance organizations might report this information in multiple instrument sections (for example, both labor and miscellaneous costs). As a result, we separated contracted services into their own categories. While we considered allowing respondents to report in the aggregate any other miscellaneous costs associated with ground ambulance services because we believed this approach may be less burdensome for organizations that track miscellaneous costs in aggregate, we believe this would introduce a large amount of reporting bias and inconsistency in reporting across organizations. Our proposals related to reporting contracted services and miscellaneous costs are described below.

Reporting Contracted Services

For contracted services, we are proposing that respondents indicate whether their organization utilizes contracted services to support a variety of tasks (section 11, question 1), the associated total annual cost for these services, and the percentage of costs attributable to ground ambulance services. The proposed data collection instrument would provide instructions to ensure that respondents do not report on contracted costs multiple times.

Reporting of Miscellaneous Costs

For other miscellaneous costs not otherwise captured in prior sections of the data collection instrument, we are proposing that respondents be able to report additional costs first using an extensive list of other potential cost categories (section 11, question 2) and then use write-in fields if necessary. Providing a pre-populated check list would help ensure the consistency and completeness of reporting across respondents.

Allocation of Miscellaneous Shared Costs

Information from ground ambulance organizations indicates that there are a number of miscellaneous costs associated with the overall operation of organizations that are shared across services. To account for these shared costs, we are proposing that respondents report an allocation factor for each contracted service, (section 11, question 1), as well as for each reported miscellaneous expense (section 11, questions 3–4) as described in the data collection instrument. We considered the alternative of asking for an overall share of miscellaneous costs associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. While this would present less burden on respondents, the share of miscellaneous costs and share of contracted services varies widely across organizations with shared services.

d. Proposed Data Collection on Revenue

Section 1834(l)(17)(A) of the Act requires the development of a data collection system to collect revenue information for ground ambulance provider and suppliers. Payments from Medicare and other health care payers are important components of total revenue for some ambulance providers and suppliers. Most ambulance providers and suppliers also have other sources of revenue in addition to payments for billed services. Based on review of existing literature and discussions with ground ambulance organizations, these primary sources of revenue include, but are not limited to: Patient out-of-pocket payments; direct public financing of fire, EMS, or other agencies; subsidies, grants, and other revenue from local, state, or federal government sources; revenue from providing services under contract; and fundraising and donations. We view total revenue as the sum of payments from health care payers and all other sources of revenue, including those listed above.

While collecting information on total revenue is essential to understanding variations in how EMS services are financed across the country, this information is not collected by Medicare or by any other entity of which we are aware. Similar to other sections of the data collection instrument, we also considered what level of data to request in this section. We are proposing to ask for total revenue in aggregate (section 13, question 1) and total revenue from paid ground ambulance transports for Medicare and, if possible, broken down by payer category for other payers (section 13, questions 2–5). We are proposing this level of detail because we believe understanding payer mix would be helpful to assess Medicare's contributions to total revenue. Based on information provided by ambulance providers and suppliers, there is variation in how patient-paid amounts were recorded in ambulance billing systems. We are proposing to ask respondents whether revenue by payer includes corresponding patient cost sharing or whether cost-sharing amounts are included in a self-pay category. For other revenue (for example, contracts from facilities and membership fees (such as those associated with community members that enroll in ambulance clubs), we are proposing to request information on additional revenue in predetermined categories and using write-in fields if necessary (section 13, question 5).

Allocation of Shared Revenues. Ground ambulance organizations vary widely in the types of other revenue sources (as noted in section 13, question 6) they receive and their share of allocated costs. For this reason, we are proposing to have respondents report the share of revenue for each category that is attributable to ground ambulance services (section 13). Similar to miscellaneous costs, we considered the alternative of asking for an overall share of other revenue sources associated with ground ambulance services or utilizing information gathered about the share of ground ambulance responses versus total responses to determine an overall allocation factor. While this would present less burden on respondents, we do not believe it would not adequately capture the revenue only associated with ground ambulance services, especially for organization with shared services.

To collect information on uncompensated care, including charity care and bad debt, we are proposing to collect information on both total and paid transports. These two measures of volume can be used to provide insight into the share of transports that are not paid. The proposed data collection instrument broadly collects information on total costs (including costs incurred in furnishing services that are ultimately paid and not paid) and total transports (again including transports that are both paid and not paid). The collected data could be used to estimate per-transport costs that can be estimated by dividing total costs by total transports, so we do

not believe it is necessary to directly collect information on uncompensated care in the revenue section of the data collection instrument.

We invite comments regarding all the proposals for data collection described in this section, including our proposals on the format, scope, elements (characteristics, utilization, and costs), collection of equipment and supply costs, and other costs.

5. Proposals for Sampling

Section 1834(l)(17)(B)(i) of the Act requires that CMS identify the ground ambulance providers and suppliers organizations that would be required to submit information under the data collection system, including the representative sample. Section 1834(l)(17)(B)(ii)(II) of the Act requires the representative sample must be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas). Under section 1834(l)(17)(B)(ii)(III) of the Act, the Secretary cannot include an individual ambulance provider and supplier in 2 consecutive years, to the extent practicable. In addition to meeting the requirements set forth in the statute, including developing a representative sample, our proposals around sampling aim to balance our need for statistical precision with reporting burden. Our proposals to meet these statutory requirements are described below, and were developed with the intention of obtaining statistical precision with the least amount of reporting burden.

Eligible Organizations. A sampling frame drawing on all ground ambulance organizations in the United States and its territories that provide ground ambulance services (that is, not just those enrolled in Medicare or billing Medicare in a given year) may be of interest conceptually, but we have not identified a data source listing all ambulance providers and suppliers that could be used as the source for a broader sampling frame. Since sections 1834(l)(17)(A) of the Act requires the Secretary to collect cost, revenue, and utilization information from providers of services and suppliers of ground ambulance services (which are Medicare specific terms with specific meaning) with the purpose of determining the adequacy of payment rates and section 1834(l)(17)(D) of the Act requires the Secretary to reduce payments to ground ambulance organizations that do not sufficiently report, we believe that the intent of the statute is to collect information under the data collection system from ground ambulance organizations that bill Medicare. Therefore, we are proposing to sample ground ambulance organizations that are enrolled in Medicare and that billed for at least one Medicare ambulance transport in the most recent year for which we have a full year of claims data prior to sampling. Since ground ambulance organizations have a full year to submit their claims to Medicare after the date of service, claims data for a calendar year are generally not considered complete until the end of the following calendar year. As a result, we would use 2017 Medicare claims and enrollment data to determine the sample for the 2020 data collection period because 2018 Medicare claims data could not be considered complete in late 2019 when the sample for the 2020 data collection period would be selected.

Sampling at the NPI level: Section 1834(l)(17) of the Act prohibits, to the extent practicable, sampling the same ambulance provider or supplier in 2 consecutive years. Although we considered sampling at a broader parent organization level for those that bill Medicare under more than one NPI, we found it was difficult to tease out of the Medicare enrollment data all the complexities of the business relationships and identify all NPIs that may be affiliated with the same parent organization. Therefore, we are proposing to select the sample at the NPI level and to include the specific NPI selected to report information. Furthermore, we propose to collect the name of the ground ambulance organization and the name and contact information of the person responsible for completing the data collection instrument for the purposes of confirming that the data submitted aligns with the intended NPI (section 2, questions 3 and 4).

Organizations using volunteer labor: Some stakeholders have suggested that ground ambulance organizations relying on volunteer labor above a certain threshold (for example, more than 10 percent of volunteer labor) should be exempt from sampling. Others have suggested that ground ambulance organizations using volunteer labor should not be excluded because those organizations that use volunteer labor are likely to be smaller and that a large share of ambulance suppliers (particularly those in rural and super rural areas) would be exempt from sampling, and therefore, our sample would not be representative as required by section 1834(l)(17)(B)(ii) of the Act. We acknowledge that analysis of the data may require additional steps to combine data submitted from ground ambulance organzations that do and do not rely on volunteers since reported labor costs would be significantly lower for ground ambulance organizations that use volunteer labor compared to those that do not. Ground ambulance organizations that use volunteer labor might have some costs related to their volunteer labor, such as stipends, but may not have others, such as an hourly wage. Therefore, we are proposing to collect information on paid and unpaid volunteer hours during a typical week using the same EMT/response staff categories used elsewhere in the data collection instrument. We believe reported hours can be converted to market rates using data from other sources, such as the Bureau of Labor Statistics' wage data. Ambulance providers and supplies that rely on volunteer labor report that it is becoming increasingly difficult to find volunteers and they are having to hire paid staff in their place, especially for the more costly labor categories, such as paramedics. Therefore, we are proposing that ambulance providers and suppliers that use any amount of volunteer labor be included in sampling. We invite comments as to whether organanizations that rely on volunteer labor should be exempt from sampling.

Sampling file. The organizational characteristics being proposed for the specific strata (volume of Medicare billed transports, service area population density, ownership, provider versus supplier status, and the share of transports that are non-emergency) can be obtained from available Medicare data. We are proposing to develop sampling files using the most recent full year of data available. For the first sample notified in 2019 and reporting in 2020, we are proposing to use 2017 claims and enrollment data. Another alternative we considered was using 2018 data, however we are not proposing this because such data may not be complete for all 2018 service dates at the time the sample for the initial year of data reporting is selected. We invite comments on our proposal to use the most recent full year of available Medicare data for sampling purposes, as described above.

Implications of historical sampling files. We expect there may be instances in which some ground ambulance organizations that were in operation at the time they were selected for the sample may cease operations by the

time data reporting begins. Similarily, we expect that some new ground ambulance organizations would start operating between the time the sample was pulled and when reporting begins. Since we propose to collect a full 12 continous months of data, these organizations would not have the data we are proposing to collect. Therefore, we are proposing that ground ambulance providers and suppliers organizations selected for the sample that were not in business for the full 12 continuous months of the data collection period would be exempt from reporting for the applicable data collection period; however, for newer ground ambulance organizations, they would be eligible for sampling and reporting in future years when they did have a full continuous 12 months of data.

We believe the above scenerios are inevitable given the significant amount of time between sampling and data reporting and invite comments on our proposed approach regarding exempting ground ambulance organizations who do not have a full 12-month continuous period of data.

Sampling rate: We are also proposing that 25 percent of ground ambulance organizations be sampled from all strata (as described below) in each of the first 4 years of reporting without replacement; that is, if an organization is sampled in Year 1, it would not be eligible for sampling again in the subsequent 3 years of data collection. We are proposing a 25 percent sampling rate because if a lower sampling rate is used, estimates of cost, revenue, and utilization from the data collected via the instrument for subgroups of ground ambulance suppliers would be of inadequate precision as described in the following section. Furthermore, our analyses illustrated that using 50 percent sampling rate yielded only marginal gains in precision over a corresponding strategy that involves sampling NPIs at a 25 percent rate while doubling the response burden. In our view, these gains are not sufficient to merit the increased burden that would be imposed by implementing a higher sampling rate. Our proposal was informed by analyses regarding the alternative sampling rates in Chapter 7 of the CAMH report. We invite comments on the proposed sampling rate of 25 percent each year.

We are also proposing to notify ground ambulance organizations that have been selected for the representative sample by listing such ground ambulance organizations on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html* and providing written notification to each selected ground ambulance organization via email or U.S. mail. Notification on the CMS website would be provided at least 30 days prior to the time the selected ambulance organization would be required to begin collecting data. For purposes of CY 2020, we will post such information on the website when the CY 2020 PFS final rule is issued. A discussion of the proposed collection and reporting requirements can be found in the next section. We are also proposing to codify the representative sample requirements in § 414.626(c).

Approach for Sampling: We considered several alternatives for developing a stratified sampling approach to facilitate data collection from specific types of ground ambulance oragnizations. Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). One approach we considered was to sample ground ambulance organizations in proportion to their volume of Medicare-billed ground ambulance services. Under this approach, organizations with more billed Medicare ground ambulance transports would be more likely to be sampled than organizations with fewer billed Medicare ground ambulance transports. The analysis of our 2016 data described in the CAMH report shows that a small number of ground ambulance organizations provided a large share of total Medicare transports. Specifically, the top 10 percent of ground ambulance organizations by volume accounted for nearly 70 percent of total Medicare ground ambulance transports. In contrast, the bottom 50 percent of ambulance providers and suppliers by volume accounted for only 3 percent of total Medicare ground ambulance transports. Under this approach, the ambulance providers and suppliers in the top 10 percent by volume would therefore be much more likely to be sampled compared to those in the bottom 50 percent by volume. While this approach would efficiently collect data on the majority of Medicare ground ambulance transports, we do not believe that this approach would comport with the requirements in section 1834(l)(17)(B)(ii)(II) of the Act to develop a representative sample of ground ambulance organizations based on the characteristics (such as ownership and geographic location) of ambulance providers and suppliers. Therefore, we do not believe that data we would be collecting using this approach would meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act.

Other alternatives for a sampling methodology include simple and stratified random samples of ground ambulance organizations. A simple random sample would include a fixed share of all ground ambulance organizations, regardless of any differences in characteristics, in each year's sample. Unlike sampling in proportion to Medicare-billed ground ambulance services, a simple random sample by definition provides a representative sample. A stratified random sample first stratifies all ground ambulance organizations based on selected characteristics and then a sample is seleced at random from the strata. The rate at which these organizations are sampled would be the same for organizations in the same stratum; however, the sampling rate may vary across strata. So long as the sampling rate is not zero within any stratum and so long as appropriate weighting adjustments are used, the sample can be considered representative.

Stratified random sampling has several advantages in that it is easy to implement and it meets the requirement that the sample be representative. It also can be used to target sampling of ambulance organziations with specific characteristics, such as ownership and geographic location, to specifically meet the requirements in section 1834(l)(17)(B)(ii)(II) of the Act that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organziation and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). It is also possible to oversample from less prevelant strata using this approach in order to facilitate more precise estimates for certain groups or comparisons between subgroups. Furthermore, unlike a simple random sample, the flexibility to vary sampling rates across strata allows the ability to account for anticipated and unanticipated rates of nonresponse.

We believe that use of a stratified random sample would comport with the statutory requirements. Therefore, we are proposing a stratified random

sample approach. Specifically, we are proposing to sample from each strata at the same rate (25 percent, as described above). We believe that data collected from a sample of this type can be adjusted via statistical weighting to be representative of all ground ambulance organizations billing Medicare for ground ambulance services even if response rates vary across the characteristics used for stratification.

For the purposes of estimating the number of responses from the sampled ground ambulance organizations, we assumed that all ground ambulance providers and suppliers organizations sampled will report, because: (1) Reporting is a requirement; (2) there is a 10 percent payment reduction for failure to sufficiently report; and (3) we believe every ground ambulance organization would want its data accounted for in the evaluation of the extent to which reported costs relate to payment rates.

Variables for Stratification: Section 1834(l)(17)(B)(ii)(II) of the Act requires that the sample be representative of the different types of providers and suppliers of ground ambulance services, such as those providers and suppliers that are part of an emergency service or part of a government organization, and the geographic locations in which ground ambulance services are funished (such as urban, rural, and low population density areas). As discussed above, we are proposing a stratified sampling approach under which we would first sample based on a set of characterícistcs of ground ambulance organizations that are described below (that is, strata) and then assess response rates based on those characteristics. Based on our analysis of information provided by ground ambulance organizations, we believe there are several important characteristics that vary among ground ambulance organizations that have implications for their costs and revenues and that could serve as strata for the purposes of sampling:

- *Provider versus supplier status.* The GAO (2012) [94] and HHS (2015) [95] reports found much higher per-transport costs for ambulance providers than those of ambulance suppliers. This suggests that the ground ambulance cost structures for ambulance providers and suppliers are fundamentally different.
- *Service area population density.* Ground ambulance organizations operate in urban, rural, and super-rural settings. As described in the CAMH report, rural and super-rural organizations tend to be smaller, transport patients at greater distances, are more likely to be government owned, and rely more heavily on volunteer labor. The population density of the area in which a ground ambulance organization is operating is expected to affect costs and revenues in a number of ways. Organizations serving rural and super-rural areas generally are likely to face lower demand for services, and thus, deliver a smaller number of transports. In addition, in rural and super-rural areas the average distance traveled per transport tends to be greater. Payment rates will also differentially impact revenue by population density because the Medicare AFS accounts for mileage and, in addition, rural and super-rural providers and suppliers receive higher temporary add-on payments.
- *Volume of transports.* If there are economies of scale, organizations providing a larger volume of services typically would face lower per-transport costs. Our analysis found that the volume distribution is highly skewed. In other words, the majority of ground ambulance organizations have a low volume of transports, but there are a small number of organizations with a very high volume of transports. Suppliers providing a large volume of transports are more likely to be for-profit organizations.
- *Ownership.* For-profit (non-government), non-profit (non-government), and government ground ambulance organizations have different business models and mixes of services, leading to different costs. Conceptually, for-profit organizations maximize profit and operate only in markets and service lines with positive margins. Non-profit and government ground ambulance organizations more broadly provide emergency service to communities and may be organized and operated in a way that does not maximize profits. The 2012 GAO report found ground ambulance organizations with more limited government support are more likely to have incentives to keep costs lower. They found that for each 2 percent decline in the average length of government subsidy there was a 2 percent decline in the average cost per transport. As a result, we expect that costs will differ based on ownership.
- *Types of services provided.* One key distinction in the types of services provided is between emergency transports and non-emergency (for example, scheduled or inter-facility) transports. For-profit suppliers are more likely than others to specialize in non-emergency scheduled transports. Another key distinction is between the level of service provided (for example BLS versus ALS).
- *Staffing.* The level of staff training (for example, EMTs versus paramedics) and the number of staff deployed is driven in part by the type and volume of calls, the availability and proximity of the nearest providers, and resources available in that community. Some suppliers use static staffing models that use set staff schedules, whereas others use a dynamic, or flexible, staffing model that calls upon staff if there is a surge in demand.
- *Use of volunteer labor.* Volunteer labor tends to be more common among small, government-based ambulance suppliers operating in rural and super-rural settings.
- *Response times.* In many cases, response times are related to the population density of the area in which they operate, with rural areas having response times more than double those of urban areas. Rural and super-rural ambulance providers and suppliers generally travel greater distances to get to patients and transport them to a hospital or the nearest appropriate facility. Variation in response times within urban areas might also occur, for example if there is significant emergency department crowding, or in extreme cases diversion that requires the ambulance to travel further to another hospital or wait with the patient until a bed is available. This extra time affects the availability of the ambulance and the staff for subsequent trips, potentially increasing response times.

As previously discussed, we are not aware of any existing data source that lists all ground ambulance organzations or one that encompasses all the characteristics that impact costs and revenues described above. Medicare claims and enrollment data is the only source of data for which we are aware that has all the providers and suppliers that bill Medicare in a given year. Several of the organizational characteristics we discuss above (including provider versus supplier status, ownership, service area population density, Medicare billed transport volume, and type of services provided) are available from Medicare data while others, such as the use of volunteer labor, staffing model, and response times are not.

We are proposing to stratify the sample based on provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural,

[94] This report is available at *https://www.gao.gov/assets/650/649018.pdf.*

[95] This report is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/Downloads/Report-To-Congress-September-2015.pdf.*

and super rural zip codes), and Medicare billed transport volume categories. Based on our analysis of the number and distribution of ground ambulance organizations' transports in 2016, we are proposing volume categories of 1 to 200, 201 to 800, 801 to 2,500, and 2,501 or more paid Medicare transports. The proposed volume categories aim to divide ground ambulance organizations into roughly similar-sized groups, while separating ground ambulance organizations with very high volume (that is, greater than 2,500 Medicare transports per year) into a separate category. We would expect that these highest-volume ground ambulance organizations may face different costs than lower-volume organizations due to economies of scale.

We are proposing to focus on these four characteristics due to data availability, and our analyses that show these to be key defining characteristics of ground ambulance organizations (which are also described in the CAMH report). Also, service area population density and Medicare billed transport volume have a direct impact on ground ambulance revenue, which is one of the categories of data that we are required to collect by section 1834(l)(17)(A) of the Act. Through Medicare claims and enrollment data, we believe we have enough information to stratify ground ambulance organizations on these four characteristics. This stratification approach results in 36 groupings of ground ambulance suppliers (defined by combinations of the three ownership categories, three service area population density categories, and four Medicare billed transport volume categories) and the same number of groupings for ambulance providers.

In some of these groupings, there are only a handful of ground ambulance organizations providing ground ambulance services with a specific set of the four characteristics. This could result in situations where few or no ground ambulance organizations with the specific set of characteristics were sampled. To minimize this risk and avoid situations where we are sampling from strata that contain only a few ambulance providers and suppliers in the entire population, we propose to stratify ground ambulance providers, which account for only 6 percent of ground ambulance organizations combined, based on service area population density only. We are proposing to use this characteristic to stratify providers rather than another characteristic because section 1834(l)(17)(A) of the Act specifically requires the Secretary to develop a data collection system to collect information on ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in section 1834(l)(12) of the Act (super rural areas).

We are also proposing to collapse the two highest Medicare ground ambulance transport volume categories (801–2500 and 2501 and more transports) into a single category (801 and more transports) for for-profit ground ambulance suppliers that primarily service super-rural areas due to the small number of ground ambulance organizations in these two volume categories. The proposed sampling rate of 25 percent aims to meet a threshold that will provide an adequate degree of precision for estimates within each strata subgroup (that is, provider versus supplier status, ownership (for-profit, non-profit, and government), service area population density (transports originating in primarily urban, rural, and super rural zip codes), and Medicare billed transport volume categories). The specific threshold is 200 expected responses in each subgroup. This number of expected responses will ensure that small to medium differences in means between groups (that is, affect size) can be detected.

A 25 percent sampling rate is expected to result in more than 200 responses in each subgroup except for ground ambulance providers (where we expect 153 responses with a 25 percent sampling rate). A 25 percent sampling rate will also result in more than 200 expected responses for other organizations not represented in the strata, including organizations providing primarily non-emergency transports and transports to and from dialysis facilities. We also expect that a 25 percent sampling rate will result in more than 200 responses for organizations that rely primarily on volunteer labor, as well as for those who do not.

We invite comments on all our proposals for sampling as described in this section, including our proposals on eligible organizations, methods for sampling, sampling at the NPI level, sampling of organizations using volunteer labor, sampling files, and sampling rates. We also invite comments on our proposals to collect data from ground ambulance organizations that bill Medicare, and the use of a stratified random sample.

6. Proposals for Collecting and Reporting of Information Under the Data Collection System

For each data collection year, section 1834(l)(17)(C) of the Act requires ground ambulance organizations identified as part of the representative sample to submit information specified under the system, with respect to a period for the year (referred to as the ''data collection period''), in a form and manner and at a time (referred to as the ''data reporting period'') specified by the Secretary. In this section, we are proposing to define the data collection period and the data reporting period. In determining when the proposed data collection and reporting periods should fall, our objectives were to: (1) Allow selected ground ambulance organizations sufficient time to collect and report the required information; and (2) collect the data for analysis in the least burdensome manner.

We considered annual (that is, 12-month) data collection periods and shorter data collection periods (for example, a 6-month period). We are proposing a 12-month data collection period because a shorter period could result in biased data due to seasonality in costs, revenue, or utilization among ground ambulance organizations.

As we stated previously, ambulance providers and suppliers constitute a diverse group of organizations with varied annual accounting practices. Accordingly, we are proposing to define the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or when an organization uses another fiscal year for accounting purposes and the organization elects to collect and report data over this period rather than the calendar year, the 12-month period that is their fiscal year that begins during the data collection year. We are proposing this data collection period based on feedback from ground ambulance organizations that stated that they prefer to collect data based on an annual accounting period (either calendar year or fiscal year) already used by the organization, and that requiring all organizations to report on the same 12-month period (for example, calendar year) could involve significant additional burden in terms of data collection and reporting. We believe that providing flexibility in collecting information under the data collection system would reduce the burden on ground ambulance organizations.

Therefore, we are proposing that the first data collection period be January 1, 2020 through December 31, 2021, with

organizations reporting on a calendar year basis collecting data from January 1, 2020 through December 31, 2021, and organizations reporting on a fiscal year basis collecting data over a continuous 12-month period of time from the start of the fiscal year beginning in calendar year 2020. Upon being notified that they are selected as part of the sample, ground ambulance organizations must notify CMS of their annual accounting period within 30 days according to the instructions in the notification letter, so that CMS is aware of when their data collection and data reporting periods would begin. We propose that respondents would additionally confirm the data collection period when reporting data via the data collection instrument (section 2, question 5).

We also propose that ground ambulance organizations would have up to 5 months to report to CMS (data reporting period) the data following the end of its 12-month data collection period. For example, if a ground ambulance organization is selected as part of the representative sample for the CY 2020 data collection year, and notifies CMS that its annual accounting period is based on a calendar year, the data collection period for this ground ambulance organization would begin on January 1, 2020 and end on December 31, 2020, and the data reporting period would be January 1, 2021 through May 31, 2021. A ground ambulance organization selected for CY 2020 that notifies CMS that its annual accounting period is based on a fiscal year basis with a fiscal year beginning on June 1, 2020 would have a data collection period from June 1, 2020 through May 31, 2021 and a data reporting period from June 1, 2021 through October 1, 2021. Since a 5-month reporting period is enough time for entities that file cost reports with Medicare to complete and submit their data, we believe it should also provide adequate time for ground ambulance organizations to report information under the data collection system to CMS. This proposal will allow providers and suppliers time to validate the information and certify the accuracy of their data required under the data collection before reporting it to CMS.

We propose to codify the data collection and reporting requirements for selected ground organizations at § 414.626(b).

Tables 30 and 31 illustrate various examples of data collection periods and the data reporting periods under our proposal. Please note that an individual ground ambulance organization would only be selected to participate in one data collection and reporting period, and that the specific data collection and reporting period dates might vary for each organization and be different than the dates noted in the tables.

TABLE 30—EXAMPLE OF A DATA COLLECTION AND REPORTING PERIOD FOR A GROUND AMBULANCE ORGANIZATION WITH A CALENDAR YEAR ACCOUNTING PERIOD

Year	Data collection period	Data reporting period
1	01/01/2020–12/31/2020	01/01/2021–05/31/2021
2	01/01/2021–12/31/2021	01/01/2022–05/31/2022
3	01/01/2022–12/31/2022	01/01/2023–05/31/2023
4	01/01/2023–12/31/2023	01/01/2024–05/31/2024

TABLE 31—EXAMPLE OF A DATA COLLECTION AND REPORTING PERIOD FOR A GROUND AMBULANCE ORGANIZATION WITH AN ACCOUNTING PERIOD NOT BASED ON A CALENDAR YEAR

Year	Data collection period	Data reporting period
1	06/01/2020–05/31/2021	06/01/2021–10/31/2021
2	06/01/2021–05/31/2022	06/01/2022–10/31/2022
3	06/01/2022–05/31/2023	06/01/2023–10/31/2023
4	06/01/2023–05/31/2024	06/01/2024–10/31/2024

We invite comments on our proposal to use a 12-month data collection period. We also invite comments on our proposal to give sampled ground ambulances the flexibility to collect data on either a calendar year basis or on the basis of the ground ambulance organization's fiscal year. In addition, we invite comments on our proposal to allow a ground ambulance organization 5 months to report the data collected during data collection period to CMS through the data collection system. We plan on addressing section 1834(l)(17)(E) of the Act, ongoing data collection, in future rulemaking.

7. Proposed Payment Reduction for Failure To Report

a. General Information and Applicable Period

Section 1834(l)(17)(D)(i) of the Act requires that beginning January 1, 2022, subject to clause (ii), the Secretary reduce the payments made to a ground ambulance organization under section 1834(l)(17) of the Act for the applicable period by 10 percent if the ground ambulance organization is required to submit data under the data collection system with respect to a data collection period and does not sufficiently submit such data. Section 1834(l)(17)(D)(ii) of the Act defines the applicable period as a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier failed to sufficiently submit information under the data collection system.

As previously discussed, we are proposing to define the data collection and data reporting periods based on the ground ambulance organization's annual accounting period (either calendar year or fiscal year). The timeline for the determination of the 10 percent reduction to payments would depend on: (1) The 12-month data collection period based on the organization's accounting period; (2) the end of the data reporting period that corresponds with the selected data collection period; and (3) the time it would take CMS to review the data to determine whether it had been sufficiently submitted. We are proposing that we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ambulance organization's data reporting period ends. This timeframe will allow CMS to assess whether the required data was sufficiently submitted.

For example, if a ground ambulance organization is selected in the first sampling year and it reports to CMS that its annual accounting period is an October 1 through September 30th fiscal year, then its data collection period would be October 1, 2020 through September 30, 2021, and the data reporting period that would apply to the ground ambulance organization would be from October 1, 2021–February 28 (or 29, if a leap year), 2022. We would make a determination regarding the sufficiency of that ground ambulance organization's reporting no later than June 1, 2022. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided by that ground ambulance organization between January 1, 2023 and December 31, 2023, because under section 1834(l)(17)(D)(iii) of the Act, the applicable period must be one year in length. As another example, if a ground ambulance organization's annual accounting period is the calendar year, its data collection period would be January 1, 2020 through December 31, 2020, the data reporting period that would apply to the ground ambulance organization would be from January 1, 2021–May 31, 2021,

and we would make a determination regarding the sufficiency of that ambulance organization's reporting no later than August 31, 2021. With this timeframe, we would propose to apply the 10 percent reduction in payments, if applicable, for ambulance services provided between January 1, 2022 and December 31, 2022. The payment reduction would always be applied to ground ambulance transports provided during the calendar year that begins following the date that we determine that the ground ambulance organization is subject to the payment reduction.

We propose that if we find the data reported is not sufficient, we would notify the ground ambulance organization that it will be subject to the 10 percent payment reduction for ambulance services provided during the next calendar year. We would interpret ''sufficient'' to mean that the data reported by the ground ambulance organization is accurate and includes all required data requested on the data collection instrument.

We are proposing to apply the 10 percent payment reduction for the appropriate calendar year as described above to ambulance fee schedule payments as described in § 414.610. The payment reduction would apply to claims for dates of service during the applicable calendar year and would be applied to the final ambulance fee schedule payment, after all other adjustments have been applied under § 414.610(c). We are proposing to codify the payment reduction by adding a new paragraph (c)(9) in § 414.610.

b. Proposed Hardship Exemption

Section 1834(l)(17)(A)(D)(iii) of the Act authorizes the Secretary to exempt a ground ambulance provider or supplier from the 10 percent payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the ground ambulance provider or supplier to submit such information in a timely manner for the specified period.

We recognize that there may be some ground ambulance organizations that have limited resources that affect their ability to report the required information, and that for these ground ambulance organizations, a 10 percent payment reduction in Medicare payments could result in significant financial hardship.

An example of this situation could be a ground ambulance organization that is located in a super rural area with such limited resources that it cannot report the required information without significantly increasing the possibility that it would need to file for bankruptcy.

Another example could be a ground ambulance organization that is located in an area that had recently experienced a natural disaster such as widespread flooding that caused the closure of a local emergency room or other facilities. Due to the increased demand for services and rerouting of patients, this ground ambulance organization might be unable to collect and report information in a timely manner.

We are proposing that ground ambulance organizations in these or other similar situations could request that CMS grant a hardship exemption, and CMS could consider granting an exemption if the ground ambulance organization could demonstrate that the significant hardship interfered with its ability to submit the required data under the data collection system.

To request a hardship exemption, we propose that a ground ambulance organization submit to CMS a completed request form, which can be found on the Ambulance Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*), and that the following information be included:

- Ambulance Provider or Supplier Name;
- NPI Number;
- Ambulance Provider or Supplier Location Address;
- CEO and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Reason for requesting a hardship exemption;
- Evidence of the impact of the hardship exemption (such as photographs, newspaper, other media articles, financial data, bankruptcy filing, etc.); and
- Date when the ground ambulance organization would be able to begin submitting information under the data collection system.

We are proposing that the completed hardship exemption request form be signed and dated by the Chief Executive Officer (CEO) or designee of the ambulance company, and be submitted as soon as possible, and not later than 90 calendar days of the date that the ground ambulance organization was notified that it will be subject to the 10 percent payment reduction as a result of not sufficiently submitting information under the data collection system. We propose that the request form be submitted to the Ambulance ODF mailbox at *AMBULANCEODF@cms.hhs.gov*. Following receipt of the request form, we are proposing to provide: (1) A written acknowledgement that the request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days of the date that we received the request. We are also proposing to codify the hardship exemption requirement at § 414.626(d).

c. Informal Review

Section 1834(l)(17)(D)(iv) of the Act requires the Secretary to establish a process under which a sampled ground organization may seek an informal review of a determination that it is subject to the 10 percent reduction. To request an informal review, we propose that a ground ambulance organization must submit the following information:

- Ground Ambulance Organization Name;
- NPI Number;
- CEO and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable);
- Ground ambulance organization's selected data collection period and data reporting period; and
- A statement of the reasons why the ground ambulance organization does not agree with CMS's determination and any supporting documentation.

We propose that the informal review request must be signed by the CEO/designee of the ground ambulance organization and be submitted within 90 calendar days of the date that the ground ambulance organization received notice regarding the 10 percent reduction in payments. We are proposing 90 calendar days to submit an informal review request to allow time for the ground ambulance organization to gather the information needed to support the request for informal review. We are proposing that the request be submitted to the Ambulance ODF mailbox at *AMBULANCEODF@cms.hhs.gov*. Following receipt of the request for informal review, we would provide: (1) A written acknowledgement using the contact information provided in the request, to the CEO and any additional designated personnel, notifying them that the ambulance provider or supplier's request has been received; and (2) a written response to the CEO and any designated personnel using the contact information provided in the request within 30 days. We are seeking comments on our proposed

informal review process. We are also proposing to codify the informal review process in § 414.610(e).

We invite comments regarding all the proposals on the payment reduction for failure to report, including the applicable period, hardship exemption, and informal review.

8. Public Availability

Section 1834(l)(17)(G) of the Act requires that the results of the data collection be posted on the CMS website, as determined appropriate by the Secretary. We are proposing to post on our website a report that includes summary statistics, respondent characteristics, and other relevant results in the aggregate so that individual ground ambulance organizations are not identifiable.

We are also proposing that the data proposed above will be made available to the public through posting on our website at least every 2 years. The 2-year timeframe would allow CMS time to analyze the data that is being reported, factoring in the various accounting periods of the first group of sampled ground ambulance organizations (which have early accounting periods in the CY 2020 data collection year).

We are proposing to post summary results by the last quarter of 2022, because we believe we may have most or all of the data requested by then. We invite comments on our proposals regarding the type of information that should be posted from the data collected and the timeline in which the results of the data collection should be posted on our website.

We invite comments regarding our proposals for public availability of the data.

9. Limitations on Review

Section 1834(l)(17)(J) of the Act provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the data collection system or identification of respondents. We are proposing to codify the limitations on review at § 414.626(g).

C. Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR)

Section 51004 of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) amended section 1861(eee)(4)(B) of the Act directing CMS to add covered conditions for intensive cardiac rehabilitation (ICR). This proposed rule includes our proposals for implementing this expansion of coverage through revisions to § 410.49(b)(1).

1. Background

Cardiac rehabilitation (CR) was developed in the 1950s from the concept of early mobilization after acute myocardial infarction (heart attack).[96] The standard of care prior to the widespread adoption of CR was bed-rest and inactivity after acute myocardial infarction.[97] In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone.[98] Referencing 1998 guidelines [99] from the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), Forman (2000) stated that ''over subsequent years the objectives of cardiac rehabilitation broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure, and stress reduction, smoking cessation, diet change, and weight loss were coupled to goals of exercise training.''

ICR, also commonly referred to as a ''lifestyle modification'' program, typically involves the same elements as traditional CR programs, but are furnished in highly structured environments in which sessions of the various components may be combined for longer periods of CR and also may be more rigorous.

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted July 15, 2008) amended Title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B. The statute specified certain conditions for these services and an effective date of January 1, 2010, for coverage of these services. Conditions of coverage for CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in § 410.49 through the CY 2010 PFS final rule with comment period (74 FR 61872–61879 and 62004–62005). These programs were designed to improve the health care of Medicare beneficiaries with cardiovascular disease.

Under § 410.49(b), Medicare part B covers CR and ICR program services for beneficiaries who have experienced one or more of the following: (1) An acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or (6) a heart or heart-lung transplant. For CR only, other cardiac conditions may be added as specified through a national coverage determination (NCD). Effective February 18, 2014, we expanded coverage of CR in NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03 20.10.1), to beneficiaries with stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable patients are defined as patients who have not had recent (≤6 weeks) or planned (≤6 months) major cardiovascular hospitalizations or procedures.

2. Statutory Authority

Section 51004 of the BBA of 2018, entitled ''Expanded Access to Medicare Intensive Cardiac Rehabilitation Programs,'' amended section 1861(eee)(4)(B) of the Act. The amendment directs us to expand the list of covered conditions for ICR beyond the 6 conditions specified in section 144(a) of the MIPPA and codified in § 410.49(b)(1).

3. Discussion of Statutory Requirements

Section 1861(eee)(4)(B) of the Act requires that, in addition to the 6 conditions specified in section 144(a) of the MIPPA, ICR be covered for beneficiaries with (1) stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks); or (2) any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

The statute explicitly states *cardiac* rehabilitation; therefore, this proposed

[96] Pashkow, FJ. Issues in Contemporary Cardiac Rehabilitation: A Historical Perspective. JACC 1993 Mar 1;21(3):822–34.

[97] Forman DE. Cardiac rehabilitation and secondary prevention programs for elderly cardiac patients. Clin Geriatr Med. 2000 Aug;16(3):619–29.

[98] Ades PA. A controlled trial of cardiac rehabilitation in the home setting using electrocardiographic and voice transtelephonic monitoring. Am Heart J. 2000 Mar;139(3):543–8.

[99] AACWR Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs, ed 3. Windsor, ON, Human Kinetics, 1998.

rule is specific to CR and ICR for cardiac conditions. As such, this proposed rule could not exceed the limits of the statute to apply CR and ICR other conditions (for example, cancer, metabolic syndrome, diabetes, peripheral artery disease, etc.).

4. Proposals for Implementation

We propose to amend § 410.49(b) to expand the covered conditions for ICR. We propose to amend § 410.49(b)(vii) to add coverage of ICR for patients with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. We also propose to specify in § 410.49(b)(vii) that coverage for CR was effective February 18, 2014 as per the NCD for Cardiac Rehabilitation for Chronic Heart Failure (Pub. 100–03 20.10.1) which was finalized on February 18, 2014 as discussed above, and that coverage for ICR was effective on enactment of the BBA of 2018 (February 9, 2018).

We also propose to add new § 410.49(b)(viii) to include coverage of ICR, in addition to CR, for other cardiac conditions as specified through an NCD. Under the existing § 410.49(b)(vii), coverage for CR may be established for other cardiac conditions through an NCD, and our proposal would extend this criterion to ICR, as well unless coverage for ICR is not supported by clinical evidence. As such, NCDs modifying the covered conditions would apply to both CR and ICR so long as clinical evidence supports coverage for CR and coverage for ICR.

It is important to note that conditions that may be considered for expanded coverage are limited to cardiac conditions and may not include other conditions (for example, cancer, metabolic syndrome, diabetes, peripheral artery disease, etc.).

5. Summary

In summary, we are proposing modifications to existing requirements under § 410.49(b) to implement the coverage changes specific to ICR. The proposals involve expanding coverage of ICR to beneficiaries with chronic heart failure as discussed above and providing for modifications to covered cardiac conditions for ICR, in addition to CR, as specified through an NCD. We invite the public to provide comments on these proposals.

D. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of Certified EHR Technology (CEHRT). We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Program.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of ''meaningful EHR user'' in regulations at 42 CFR 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the CY 2019 PFS final rule (83 FR 59452, 59703 through 59704), we established for 2019 that Medicaid EPs are required to report on any 6 eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. We also adopted the Merit-based Incentive Payment System (MIPS) requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). We explained that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, the EP may report on any 6 eCQMs that are relevant.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2020

We annually review and revise the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In section III.I.3.h.(2)(b)(i) of this proposed rule, we propose to amend the list of available eCQMs for the CY 2020 performance period. To keep eCQM specifications current and minimize complexity, we propose to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. Specifically, we propose that the eCQMs available for Medicaid EPs in 2020 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established under MIPS for the CY 2020 performance period.

In previous years, CMS proposals to align the list of eCQMs for MIPS and the Medicaid Promoting Interoperability Program for EPs received positive comments that indicated that alignment between these two programs would help reduce health care provider reporting burden (83 FR 59702). These comments thus suggest that aligning the eCQM lists might encourage EP participation in the Medicaid Promoting Interoperability Program by giving Medicaid EPs that are also MIPS eligible clinicians the ability to report the same eCQMs as they report for MIPS. Not aligning the eCQM lists could lead to increased burden, because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program if they opt to report on newly added eCQMs for MIPS. In addition, we believe that aligning the eCQMs available in each program would help to ensure the most uniform application of up-to-date clinical standards and guidelines possible.

We anticipate that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs would report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on the available eCQMs for 2020. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications.

For 2020, we propose to again require (as we did for 2019) that Medicaid EPs report on any 6 eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. This policy of allowing Medicaid EPs to report on any 6 measures relevant to their scope of practice would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS

eligible clinicians who elect to submit eCQMs must generally submit data on at least 6 quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We refer readers to § 414.1335(a) for the data submission criteria that apply to individual MIPS eligible clinicians and groups that elect to submit data with other collection types.

In addition, as we did for 2019, we propose that for 2020, EPs in the Medicaid Promoting Interoperability Program would be required to report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). This policy would improve alignment with the requirements for the MIPS quality performance category for eligible clinicians using the eCQM collection type. We also propose that if no outcome or high priority measures are relevant to a Medicaid EP's scope of practice, the clinician may report on any 6 eCQMs that are relevant, as was the policy in 2019.

In the CY 2019 PFS final rule (83 FR 59702 and 59704), we established the following three methods to identify which of the available measures are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program. We propose to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2020:

- The same set of measures that are identified as high priority measures for reporting on the quality performance category for eligible clinicians participating in MIPS.
- All e-specified measures from the previous year's core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (Child Core Set) or the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as ''Core Sets'') that are also included on the MIPS list of eCQMs.

Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These Core Sets are composed of measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. The MIPS eCQM list includes several, but not all, of the measures in the Core Sets. Because the Core Sets are released at the beginning of each year, it is not possible to update the list of high-priority eCQMs with those added to the current year's Core Sets.

The eCQMs that would be available for Medicaid EPs to report in 2020, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under our proposal are: CMS2, ''Preventive Care and Screening: Screening for Depression and Follow-Up Plan''; CMS122, ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)''; CMS125, ''Breast Cancer Screening''; CMS128, ''Anti-depressant Medication Management''; CMS136, ''Follow-Up Care for Children Prescribed ADHD Medication (ADD)''; CMS137, ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment''; CMS153, ''Chlamydia Screening for Women''; CMS155, ''Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents''; and CMS165, ''Controlling High Blood Pressure.''

- Through an amendment to § 495.332(f), we gave each state the flexibility to identify which of the eCQMs available for reporting in the Medicaid Promoting Interoperability Program are high priority measures for Medicaid EPs in that state, with review and approval by CMS, through the State Medicaid HIT Plan (SMHP). States are thus able to identify high priority measures that align with their state health goals or other programs within the state.

All eCQMs identified via any of these three methods are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2019. As noted above, we propose to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2020. We invite comments as to whether any of these methods should be altered or removed, or whether any additional methods should be considered for 2021.

We also propose that the 2020 eCQM reporting period for Medicaid EPs who have demonstrated meaningful use in a prior year be a minimum of any continuous 274-day period within CY 2020. This 274-day eCQM reporting period corresponds to the 9-month period from January 1, 2020 to September 30, 2020. Medicaid EPs would not be required to use that exact reporting period, but would be able to use any continuous 274-day period within CY 2020. Medicaid EPs could also use a longer eCQM reporting period in CY 2020, up to the full calendar year. In addition, states would be required to allow sufficient time for EPs to attest for program year 2020 beyond January 1, 2021 so that EPs may, should they choose to do so, select EHR and eCQM reporting periods that take place at any time within the 2020 calendar year through December 31, 2020.

We are proposing this eCQM reporting period for 2020 to improve state flexibility in the penultimate year of the Medicaid Promoting Interoperability Program, and to facilitate an orderly end of the program in 2021. In the CY 2019 PFS final rule, we established that the eCQM reporting period for Medicaid EPs in 2021 will be a minimum of any continuous 90-day period within CY 2021, and also established that the end date for this period must fall before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability payments to EPs by the December 31, 2021 statutory deadline (83 FR 59704 through 59706). When proposing that policy, we received comments that asked us to consider an eCQM reporting period shorter than a full year in 2020. Commenters stated that a full-year reporting period may create significant backlogs of 2020 and 2021 attestations in 2021 that may create difficulty for states to issue payments by the statutory deadline (83 FR 59705). We continue to believe that longer reporting periods create more useful data for quality measurement and improvement because they give states a broader picture of a health care provider's care and patient outcomes. However, we agree that a full-year eCQM reporting period in 2020 might unnecessarily burden states as they would need to issue incentive payments and implement systems changes for 2021 in a timely manner.

This proposal would allow states to accept attestations for program year 2020 as early as October 1, 2020 from Medicaid EPs who choose to use an eCQM reporting period early in the year, and thus could give states additional time to prepare for 2021 and the end of the Medicaid Promoting Interoperability Program. Even though states would also still have to allow EPs to submit attestations for 2020 in 2021, we believe that allowing some EPs to attest sooner could accelerate states' pre-payment verification and payment process. We considered whether to propose a Medicaid EP eCQM reporting period for 2020 from January 1, 2020 through September 30, 2020, with no flexibility for EPs to select an alternative 274-day eCQM reporting period. We also

considered whether to propose a date prior to December 31, 2020 by which all Medicaid EP EHR and eCQM reporting periods for 2020 must end. While either of these alternatives might have further helped to ensure that all states would have additional time to prepare for 2021, we decided not to propose either of them because we wanted to preserve as much flexibility as possible for Medicaid EPs. However, we seek comment, especially from states and Medicaid EPs, about whether either of these alternatives might be preferable to our proposal.

We note that states submit their attestation deadlines to CMS each year as part of their SMHPs. We do not believe that this proposal would create any additional burden on EPs or CEHRT vendors, as CEHRT should be able to report eCQM data from any length of time.

We propose that, in 2020, the eCQM reporting period for Medicaid EPs demonstrating meaningful use for the first time, which was established in the final rule entitled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017'' (80 FR 62762, 62892) (hereinafter known as the ''Stage 3 final rule''), would remain any continuous 90-day period within the calendar year, as in previous years.

3. Objective 1: Protect Patient Health Information in 2021

In the Stage 3 final rule (80 FR 62762, 62832), we established Meaningful Use Objective 1 as ''Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative, and physical safeguards.'' As specified at § 495.24(d)(1)(i)(B), to meet that objective, EPs must meet the associated measure to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

In the Stage 3 final rule, we explained that this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period, though if it occurs after the EHR reporting period it must occur before the provider attests to meaningful use of CEHRT or before the end of the calendar year, whichever comes first (80 FR 62831). In practice, this means that EPs do not attest to meaningful use of CEHRT before completing this measure.

As discussed above, states must issue all Medicaid Promoting Interoperability Program incentive payments by the statutory deadline of December 31, 2021. States can establish state-specific deadlines for Medicaid EPs to attest to the state regarding meaningful use of CEHRT in CY 2021. However, due to changes CMS made in prior rulemaking to the Medicaid Promoting Interoperability Program EHR and eCQM reporting periods for 2021, all states must set attestation deadlines on or before October 31, 2021. *See* 42 CFR 495.4 (definition of ''EHR reporting period'') and 495.332(f)(3) and (4), and 83 FR 59704 through 59705. Because all EPs are therefore expected to attest to meaningful use of CEHRT before the end of CY 2021, Medicaid EPs would no longer have the option of completing the security risk analysis at the end of the calendar year, and would likely have to complete it well before December 2021. For example, in a state with an attestation deadline of October 1, 2021, a Medicaid EP would have to conduct the security risk analysis by September 30, 2021. Stakeholders have given us feedback that most security risk analyses are conducted on a clinic or practice level, which may include EPs and non-EPs. As we noted in the Stage 3 final rule, ''[a]n organization may conduct one security risk analysis or review which is applicable to all EPs within the organization, provided it is within the same calendar year and prior to any EP attestation for that calendar year. However, each EP is individually responsible for their own attestation and for independently meeting the objective. Therefore, it is incumbent on each individual EP to ensure that any security risk analysis or review conducted for the group is relevant to and fully inclusive of any unique implementation or use of CEHRT relevant to their individual practice'' (80 FR 62794).

If an EP or practice typically conducts the security risk analysis at the end of each year, the CY 2021 timeline for attesting to meaningful use of CEHRT may create burden for all Medicaid EPs and for non-EP health care providers within the same organization as Medicaid EPs, and may not be optimal for protecting information security, because it could disrupt the intervals between security risk analyses. As we explained in the Stage 3 final rule, a security risk analysis is not a discrete item in time, but a comprehensive analysis covering the full period of time for which it is applicable; and the annual review of such an analysis is similarly comprehensive. In other words, the analysis and review, no matter when they are conducted, should *not* be just a ''point in time'' exercise, and instead should cover a span of the entire year, including a review planning for future system changes within the year or a review of prior system changes within the year (80 FR 62831). However, EPs that typically conduct the security risk analysis in December of each calendar year might conduct one security risk analysis in December 2020, and then have to conduct another one well before December 2021, if the analysis must be completed before the EP attests to meaningful use of CEHRT for CY 2021. We believe that security risk analyses are most effective for data security when conducted on a regular schedule. In addition, practice locations may have ongoing contracts or processes in place to perform a security risk analysis at the same time each year. We do not wish to create burden for EPs and non-EPs related to changing those processes to meet the CY 2021 Medicaid Promoting Interoperability Program attestation timelines.

Therefore, we are proposing to allow Medicaid EPs to conduct a security risk analysis at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state. A Medicaid EP who has not completed a security risk analysis for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required analysis by December 31, 2021. Under this proposal, states could require Medicaid EPs to submit evidence that the security risk analysis has been completed as promised, even after the incentive payment has been issued. In addition, states could require EPs to attest that if a security risk analysis is not completed by December 31, 2021, they will voluntarily rescind their attestation to meaningful use of CEHRT and return the incentive payment. If this proposal is finalized as proposed, we would work with states to develop post-payment verification and audit processes that meet CMS due diligence requirements, including those in §§ 495.318 and 495.368, and generally to ensure that incentive payments are made properly. We remind states that as a condition of receiving enhanced federal financial participation (FFP), they are required to demonstrate to the satisfaction of HHS that they are conducting adequate

oversight of the program, including routine tracking of meaningful use attestations (*See* § 495.318(b)). States are also reminded that they must submit a description of the methodology used to verify that EPs have meaningfully used CEHRT for CMS approval as part of their SMHP. (*See* § 495.332(c)). In the final rule titled ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program'' (75 FR 44313), CMS explained that states are expected to ''look behind'' provider attestations, and that this would require audits both pre- and post-payment (75 FR 44515). These requirements and expectations would not change under this proposal.

4. Clarification

In the CY 2019 PFS final rule (83 FR 59702), in the list of high priority eCQMs that are available for Medicaid EPs to report in 2019 because they are both part of the Core Sets and on the MIPS list of eCQMs, we inadvertently listed ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment'' as ''CMS4.'' It should have read ''CMS137, 'Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.' ''

E. Medicare Shared Savings Program

As required under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 9, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies including redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. In the CY 2019 PFS final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in selecting their primary care provider and in the use of that selection for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715). In the CY 2018 PFS final rule (82 FR 53209 through 53226), we finalized revisions to several different policies under the Shared Savings Program, including the assignment methodology, quality measure validation audit process, use of the skilled nursing facility (SNF) 3-day waiver, and handling of demonstration payments for purposes of financial reconciliation and establishing historical benchmarks. In addition, in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77255 through 77260, and 82 FR 53688 through 53706, respectively), we finalized policies related to the Alternative Payment Model (APM) scoring standard under the Merit-Based Incentive Payment System (MIPS), which reduced the reporting burden for MIPS eligible clinicians who participate in MIPS APMs, such as the Shared Savings Program.

As a general summary, in this CY 2020 PFS proposed rule, we:

- Discuss aligning the Shared Savings Program quality measure set with proposed changes to the Web Interface measure set under MIPS per previously-finalized policy;
- Propose a change to the claims-based measures;
- Solicit comment on aligning the Shared Savings Program quality score with the MIPS quality performance category score; and
- Propose a technical change to correct a cross-reference within a provision of the Shared Savings Program's regulations on the skilled nursing facility (SNF) 3-day rule waiver, to conform with amendments to § 425.612 that were adopted in the December 2018 final rule;

1. Quality Measurement

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule, we established a quality measure set spanning four domains: Patient experience of care, care coordination/patient safety, preventive health, and at-risk population (76 FR 67872 through 67891). Since the Shared Savings Program was established, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through the annual rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. For performance year 2019, 23 quality measures will be used to determine ACO quality performance (83 FR 59707 through

59715). The information used to determine ACO performance on these quality measures will be submitted by the ACO through the CMS Web Interface, calculated by us from administrative claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey.

Eligible clinicians who are participating in an ACO and who are subject to MIPS (MIPS eligible clinicians) will be scored under the APM scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track (or payment model within a track, such as Levels A–D of the BASIC Track) of the Shared Savings Program that is not an Advanced APM, as well as those participating in an ACO in a track (or payment model within a track) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

b. Proposed Changes to the CMS Web Interface and Claims-Based Measures

Since the Shared Savings Program was first established in 2012, we have updated the quality measure set to reduce reporting burden and focus on more meaningful, outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2019 PFS final rule (83 FR 59711). In the CY 2019 PFS final rule, we explained that in developing the proposed changes to the quality measure set for 2019, we had considered the agency's efforts to streamline quality measures, reduce regulatory burden and promote innovation as part of the agency's Meaningful Measures initiative (*see* CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html*). We also noted that under the Meaningful Measures initiative, we have committed to assessing only those core issues that are most vital to providing high-quality care and improving patient outcomes, with the aim of focusing on high-priority measures, reducing unnecessary burden on providers, and putting patients first. The changes made in the CY 2019 PFS final rule reduced the Shared Savings Program quality measure set from 31 to 23 measures. Currently, more than half of the 23 Shared Savings Program quality measures are outcome and high-priority measures, including:

- Patient-experience of care measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience.
- Outcome measures supporting effective communication and care coordination, such as unplanned admission and readmission measures.
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes.

As we stated in the CY 2019 PFS final rule (83 FR 59713), we seek to align the Shared Savings Program measure set with changes made to the CMS Web Interface measures under the Quality Payment Program. In the 2017 PFS final rule, we stated that we do not believe it is beneficial to propose CMS Web interface measures for ACO quality reporting separately (81 FR 80499). Therefore, to avoid confusion and duplicative rulemaking, we adopted a policy that any future changes to the CMS Web interface measures would be proposed and finalized through rulemaking for the Quality Payment Program, and that such changes would be applicable to ACO quality reporting under the Shared Savings Program. In accordance with the policy adopted in the CY 2017 PFS final rule (81 FR 80501), we are not making any specific proposals related to changes in CMS Web Interface measures reported under the Shared Savings Program. Rather, we refer readers to Appendix 1, Table C (Existing Quality Measures Proposed for Removal Beginning with the 2022 MIPS Payment Year) and Table Group A (New Quality Measures Proposed for Addition Beginning with the 2022 MIPS Payment Year) of this proposed rule for a complete discussion of the proposed changes to the CMS Web Interface measures for performance year 2020 (2022 MIPS Payment Year). Based on the changes being proposed in Appendix 1, Table C of this proposed rule, ACOs would no longer be responsible for reporting the following measure for purposes of the Shared Savings Program starting with reporting for performance year 2020:

- ACO–14 Preventive Care and Screening Influenza Immunization

In the event we do not finalize the removal of this measure, we would maintain the measure with the ''substantive'' change described in Appendix 1, Table C (Previously Finalized Quality Measures Proposed for Removal in the 2022 Payment Year and Future Years) of this proposed rule. We have reviewed the proposed ''substantive'' change and we do not believe that this change to the measure would require that we revert the measure to pay-for-reporting for the 2020 performance year as we could create a historical benchmark.

Additionally, in section III.I.3.B.(1) of this proposed rule, we are proposing to add the following measure to the CMS Web Interface for purposes of the Quality Payment Program:

- ACO–47 Adult Immunization Status

Based on the policies being proposed for purposes of MIPS in Appendix 1, Table Group A of this proposed rule, Shared Savings Program ACOs would be responsible for reporting the Adult Immunization Status measure (ACO–47) starting with quality reporting for performance year 2020. Consistent with our existing policy regarding the scoring of newly introduced quality measures, this measure would be pay-for-reporting for all ACOs for 2 years (performance years 2020 and performance year 2021). The measure would then phase into pay-for-performance beginning in performance year 2022 (§ 425.502(a)(4)).

In section III.J.3.c.(1)(d) of this rule, we note that as discussed in Table DD (Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year), we have determined based on extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (ACO–17) measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified in the CY 2018 Quality Payment Program final rule (82 FR 54164) and is unduly burdensome on clinicians. Moreover, due to the current guidance, we are unable to rely on historical data to benchmark the measure. Therefore, for the 2018 performance year we are designating the measure pay-for-reporting in accordance with § 425.502(a)(5). Additionally, in section III.J.3.c.(1)(d) of this proposed rule, we are proposing to update the CMS Web Interface measure numerator guidance for purposes of the Quality Payment Program. To the extent that this proposed change constitutes a change to the Shared Savings Program measure set after the start of the 2019 performance period, we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to modify the measure as proposed in Table DD because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure,

as modified in the CY 2018 QPP final rule, and unduly burdensome on clinicians. If this modification is finalized as proposed, consistent with our discussion in the CY 2018 PFS final rule, we expect we would be able to use historical data reported on the measure to establish an appropriate 2019 benchmark that aligns with the updated specifications (82 FR 53214 and 53215) and the measure would be pay-for-performance for performance year 2019 and subsequent year.

In addition, we note that AHRQ, which is the measure steward for ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment), made an update to the measure that will require a change to the measure specifications for performance year 2020.[100] Currently, ACO–43 assesses the risk adjusted rate of hospital discharges for acute PQI conditions with a principal diagnosis of dehydration, bacterial pneumonia, and urinary tract infection. The updated measure will only include two conditions, bacterial pneumonia and urinary tract infection. This measure is a composite measure and the rate of hospital discharges is approximately equal to the sum of the rates of hospital discharges for each of its components. Therefore, the removal of dehydration will likely decrease the composite rate by approximately the rate of dehydration discharges. Based on this substantive change, we propose to redesignate ACO–43 as pay-for-reporting for 2020 and 2021 consistent with our policy under § 425.502(a)(4), which provides that a newly introduced measure is set at the level of complete and accurate reporting for the first two reporting periods the measure is required. However, we also considered creating a benchmark using historical data for bacterial pneumonia and urinary tract infection and keeping the measure pay-for-performance. As this is a claims-based measure, we have access to historical data for both bacterial pneumonia and urinary tract infection so we would be able to create a historical benchmark for the revised measure. However, we believe that changes to measures impact how ACOs, their ACO participants, and ACO provider/suppliers allocate their resources and redesign their care process to improve quality of care for their beneficiaries. As a result, our proposal to revert the measure to pay-for-reporting for 2 years will give ACOs time to refine care processes and educate clinicians while also gaining experience with the refined composite measure and understanding of performance under revised benchmarks prior to the start of a pay for performance year.

We seek comment on this proposal and the alternative approach considered.

Table 32 shows the Shared Savings Program quality measure set for performance year 2020 and subsequent performance years that would result if the proposals in section III.I.3.B.(1) of this proposed rule are finalized, including the phase-in schedule for the proposed Adult Immunization Status measure (ACO–47).

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[100] *https://www.qualityindicators.ahrq.gov/News/Retirement%20Notice_v2019_Indicators.pdf.*

TABLE 32: Measure Set for Use in Establishing the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2020

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/Caregiver Experience	ACO - 1	CAHPS: Getting Timely Care, Appointments, and Information		NQF N/A AHRQ	Survey	R	P	P
	ACO - 2	CAHPS: How Well Your Providers Communicate		NQF N/A AHRQ	Survey	R	P	P
	ACO - 3	CAHPS: Patients' Rating of Provider		NQF N/A AHRQ	Survey	R	P	P
	ACO - 4	CAHPS: Access to Specialists		NQF #N/A CMS/AHRQ	Survey	R	P	P
	ACO - 5	CAHPS: Health Promotion and Education		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 6	CAHPS: Shared Decision Making		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 7	CAHPS: Health Status/Functional Status		NQF #N/A AHRQ	Survey	R	R	R
	ACO - 34	CAHPS: Stewardship of Patient Resources		NQF #N/A AHRQ	Survey	R	P	P
	ACO - 45	CAHPS: Courteous and Helpful Office Staff		NQF #N/A AHRQ	Survey	R	R	P
	ACO - 46	CAHPS: Care Coordination		NQF #N/A AHRQ	Survey	R	R	P
Care Coordination/ Patient Safety	ACO - 8	Risk-Standardized, All Condition Readmission		Adapted NQF #1789 CMS	Claims	R	R	P
	ACO - 38	Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions		NQF#2888 CMS	Claims	R	R	P
	ACO - 43	Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) (version with additional Risk Adjustment)		AHRQ	Claims	R	R	P
	ACO - 13	Falls: Screening for Future Falls		NQF #0101 NCQA	CMS Web Interface	R	P	P
AIM: Better Health for Populations								
Preventive Health	ACO-47	Adult Immunization Status	✓	NQF #N/A NCQA	CMS Web Interface	R	R	P
	ACO - 17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention		NQF #0028 AMA-PCPI	CMS Web Interface	R	P	P
	ACO - 18	Preventive Care and Screening: Screening for Depression and Follow-up Plan		NQF #0418 CMS	CMS Web Interface	R	P	P
	ACO - 19	Colorectal Cancer Screening		NQF #0034 NCQA	CMS Web Interface	R	R	P
	ACO - 20	Breast Cancer Screening		NQF #2372 NCQA	CMS Web Interface	R	R	P
	ACO - 42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease		NQF #N/A CMS	CMS Web Interface	R	R	R
Clinical Care for	ACO - 40	Depression Remission at Twelve		NQF #0710	CMS Web	R	R	R

Domain	ACO Measure #	Measure Title	New Measure	NQF #/Measure Steward	Method of Data Submission	Pay for Performance Phase-In R – Reporting P – Performance PY1	PY2	PY3
At Risk Population - Depression		Months		MNCM	Interface			
Clinical Care for At Risk Population - Diabetes	ACO-27	Diabetes Hemoglobin A1c (HbA1c) Poor Control (>9%))		NQF #0059 NCQA	CMS Web Interface	R	P	P
Clinical Care for At Risk Population - Hypertension	ACO - 28	Hypertension : Controlling High Blood Pressure		NQF #0018 NCQA	CMS Web Interface	R	P	P

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The net result, if the proposals in section III.I.3.b.(1) of this proposed rule are finalized, would be a set of 23 measures on which ACOs' quality performance would be assessed for performance year 2020 and subsequent performance years. The 4 domains would include the following numbers of quality measures (See Table 33):

- Patient/Caregiver Experience of Care-10 measures.
- Care Coordination/Patient Safety-4 measures.
- Preventive Health-6 measures.
- At Risk Populations-3 measures.

Table 33 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes.

TABLE 33: Number of Measures and Total Points for Each Domain within the Shared Savings Program Quality Performance Standard, Starting with Performance Years during 2019

Domain	Number of Individual Measures	Total Measures for Scoring Purposes	Total Possible Points	Domain Weight
Patient/Caregiver Experience	10	10 individual survey module measures	20	25%
Care Coordination/ Patient Safety	4	4 measures	8	25%
Preventive Health	6	6 measures	12	25%
At-Risk Population	3	3 individual measures	6	25%
Total in all Domains	23	23	46	100%

c. Seeking Comment on Aligning the Shared Savings Program Quality Score With the MIPS Quality Score

As discussed above, our principal goal in selecting quality measures for the Shared Savings Program has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. The Shared Savings Program quality measure set currently consists of 23 measures spanning four domains that are submitted by the ACO through the CMS Web Interface, calculated by us for ACOs from administrative claims data, and collected via a patient experience of care survey referred to as the CAHPS for ACOs Survey. The number of measures within the four domains has changed over time to reflect changes in clinical practice, move towards more outcome and high-priority measures, align with other quality reporting programs, and reduce burden; however, the overall structure of four equally weighted measure domains has remained consistent in determining ACOs' quality performance since the Shared Savings Program was established in 2012. As provided in section 1899(d)(2) of the Act and § 425.502(a) of the Shared Savings Program regulations, ACOs must meet a quality performance standard to qualify to share in savings. Currently, the quality performance standard is based on an ACO's performance year rather than financial track. The quality performance standard is defined at the level of full and complete reporting (pay-for-reporting (P4R)) for the first performance year of an ACO's first agreement period. In the second or subsequent years of the first agreement period and all years of subsequent agreement periods, quality measures are scored as pay-for-performance (P4P) according to the phase-in schedule for the specific measure and the ACO's performance year in the Shared Savings Program:

- For all performance years, ACOs must completely and accurately report all quality data used to calculate and assess their quality performance.
- CMS designates a performance benchmark and minimum attainment level for each P4P measure and establishes a point scale for the measure. An ACO's quality performance for a measure is evaluated using the appropriate point scale, and these measure specific scores are used to calculate the final quality score for the ACO.
- ACOs must meet minimum attainment (defined as the 30th percentile benchmark for P4P measures) on at least one measure in each domain

to be eligible to share in any savings generated (§ 425.502(d)(2)(iii)(A)).

ACOs are rewarded for their quality performance on a sliding scale on which higher levels of quality performance translate to higher rates of shared savings and, depending on the track under which an ACO is participating, may result in lower rates of shared losses. In addition, ACOs that demonstrate significant quality improvement on measures in a domain are eligible to receive a quality improvement reward (§ 425.502(e)(4)). Specifically, for each domain, ACOs can be awarded up to four additional points for quality performance improvement on the quality measures within the domain. These bonus points are added to the total points that an ACO achieves for the quality measures within that domain, but the total number of points cannot exceed the maximum total points for the domain.

In the CY 2018 Quality Payment Program final rule, we finalized a policy for the 2018 performance period and subsequent performance periods that the quality performance category under the MIPS APM Scoring Standard for MIPS eligible clinicians participating in a Shared Savings Program ACO will be assessed based on measures collected through the CMS Web Interface and the CAHPS for ACOs survey measures (82 FR 53688 through 53706). We assign the same MIPS quality performance category score to each Tax Identification Number (TIN)/National Provider Identifier (NPI) in a Shared Savings Program ACO based on the ACO's total quality score derived from the measures reported via the CMS Web Interface and the CAHPS for ACOs survey. Eligible clinicians in a Shared Savings Program ACO will receive full credit for the improvement activities performance category in 2020 based on their performance of improvement activities required under the Shared Savings Program. In addition, ACO participants report on the Promoting Interoperability performance category at the group or solo practice level for eligible clinicians subject to Promoting Interoperability performance category. Data for the Promoting Interoperability performance category is reported by ACO participants at the TIN level and is then weighted and aggregated to get a single ACO score for the performance category that applies to all eligible clinicians participating in the ACO. These three categories in the APM scoring standard are weighted as follows: Quality is 50 percent, Improvement Activities is 20 percent, and Promoting Interoperability is 30 percent. Eligible Clinicians participating in the Shared Savings Program are not assessed under the MIPS cost performance category as these eligible clinicians are already subject to cost and utilization performance assessments as part of the Shared Savings Program. Therefore, the cost performance category is weighted at zero percent.

Eligible clinicians who reassign their billing rights to an ACO Participant TIN in an Advanced APM (Track 2, Track 1+ ACO Model, BASIC Track Level E, and ENHANCED Track) and who are included on the Advanced APM Participation List on at least one of three snapshot dates (March 31, June 30, and August 31) during the performance year may become Qualifying APM Participants (QPs) for the year, if they meet payment or patient count thresholds. If these eligible clinicians attain QP status for the performance year via their participation in the Shared Savings Program ACO, they would receive an APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment for the related payment year. However, they would be required to report quality for purposes of the Shared Savings Program financial reconciliation.

We recognize that ACOs and their participating providers and suppliers have finite resources to dedicate to engaging in efforts to improve quality and reduce costs for their assigned beneficiary population. Although CMS has worked to align policies under the Shared Savings Program with the Quality Payment Program, we recognize that some differences in program methodologies for the Shared Savings Program and MIPS remain and could potentially create conflicts for MIPS eligible clinicians in an ACO who are attempting to strategically transform their respective practices to earn shared savings under the terms of the Shared Savings Program and a positive payment adjustment under MIPS. Currently, under the Shared Savings Program, ACOs in performance years other than the first performance year of their first agreement period are allocated up to two points for quality measures that are pay-for-performance, according to where their performance falls, relative to benchmark deciles. Incomplete reporting of any CMS Web Interface measure will result in zero points for all CMS Web Interface measures and the ACO will fail to meet the quality performance standard for the performance year. Similarly, if a CAHPS for ACOs Survey is not administered and/or no data is transmitted to CMS, zero points will be earned for all Patient/Caregiver Experience measures and the ACO will fail to meet the quality standard for the performance year. The quality measure set for the Shared Savings Program also includes certain claims-based measures that are not part of the MIPS quality performance category, and we currently calculate performance rates on these claims-based measures for purposes of determining an ACO's overall quality score under the Shared Savings Program.

In contrast, when a group submits measures for the MIPS quality performance category via the CMS Web Interface, each measure is assessed against its benchmark to determine how many points the measure earns. For the 2019 MIPS performance period, a group can receive between 3 and 10 points for each MIPS measure (not including bonus points) that meets the data completeness and case minimum requirements by comparing measure performance to established benchmarks. If a group fails to meet the data completeness requirement on one of the CMS Web Interface measures, it receives zero points for that measure; however, all other CMS Web Interface measures that meet the data completeness requirement are assessed against the measure benchmarks, and the points earned across all measures are included in the quality performance category score. Currently, the only administrative claims-based measure used in MIPS is the All-Cause Readmission measure, which is only calculated for groups with 16 or more eligible clinicians. These differences between the Shared Savings Program quality measure set and the MIPS quality measure set highlight the different quality measurement approaches for which Shared Savings Program ACOs must simultaneously evaluate, prioritize, and target resources that may be better directed toward patient care if the quality measurement approaches under the Shared Savings Program and MIPS were more closely aligned.

We believe that using a single methodology to measure quality performance under both the Shared Savings Program and the MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients, and reduce burden as ACOs would be able to track to a smaller measure set under a unified scoring methodology. Accordingly, we are soliciting comment on how to potentially align the Shared Savings Program quality reporting requirements and scoring methodology more closely with the MIPS quality reporting requirements and scoring methodology.

First, we are requesting comments on replacing the Shared Savings Program quality score with the MIPS quality performance category score, for ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM (currently, Track 1 and BASIC Track Levels A, B, C and D). Allowing for a single quality performance score for both programs would eliminate the need for ACOs to focus their resources for quality improvement on maximizing performance under two separate quality reporting requirements with distinct scoring methodologies. Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. For Shared Savings Program quality scoring purposes, we could utilize the MIPS quality performance category score, converted to a percentage of points earned out of the total points available, as the ACO's quality score for purposes of financial reconciliation under the Shared Savings Program. We note that for performance year 2017 (the only year from which we have complete data available), the weighted mean MIPS quality performance category score for ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM) was 45.01 and the weighted median MIPS quality performance score for these ACOs was 46.8, out of a possible 50 points assigned for the quality performance category.

ACOs in tracks (or payment models within a track) that meet the definition of an Advanced APM whose eligible clinicians are QPs for the year and thus are excluded from the MIPS reporting requirements, do not receive a quality performance category score under MIPS. Instead the quality data the ACO reports to the CMS Web Interface is used along with the ACO's CAHPS data and the administrative claims-based measures calculated by us, solely for the purpose of scoring the quality performance of the ACO under the Shared Savings Program quality scoring methodology. As an alternative, given that we currently collect the necessary data from these ACOs, we could also calculate a quality score for these ACOs under the MIPS scoring methodology, and use this score to assess the quality performance of the ACO for purposes of the Shared Savings Program. Using this score would also inform eligible clinicians participating in these ACOs of their MIPS quality score in the event that they lose QP status and are scored under the MIPS APM scoring standard.

Utilizing a MIPS quality performance category score to assess the quality performance for purposes of the Shared Savings Program ACOs in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether eligible clinicians participating in the ACO obtain QP status and are excluded from MIPS, nor would it change the ACO participant TINs' eligibility to receive Advanced APM incentive payments. Rather, under this approach we would utilize the same scoring methodology to determine the quality performance, for Shared Savings Program ACOs that are participating in Advanced APMs as would be used to assess the quality performance of ACOs in Shared Savings Program tracks (or payment models within a track) that do not meet the definition of an Advanced APM, creating further alignment of performance results and further synergies between the Shared Savings Program and MIPS. We welcome comment on the approach of using the MIPS quality performance category score to assess quality performance for purposes of the Shared Savings Program quality performance standard for ACOs that are in tracks (or payment models within a track) that qualify as Advanced APMs. We also welcome comment on potential alternative approaches for scoring Shared Savings Program quality performance in a way that more closely aligns with MIPS.

In addition, we note that we are also soliciting comment on simplifying MIPS by implementing a core measure set using administrative claims-based measures that can be broadly applied to communities or populations and developing measure set tracks around specialty areas or public health conditions to standardize and provide more cohesive reporting and participation. We refer readers to section III.I.3.a.(3) of this proposed rule for more information on these approaches.

Currently, for ACOs in tracks (or payment models within a track) that do not meet the definition of an Advanced APM, the MIPS quality performance category score is calculated based on the measures reported by the ACO via the CMS Web Interface and the CAHPS for ACO survey measures. In section III.I.3.b.(1)(ii) of this proposed rule, we are proposing to add the MIPS All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the MIPS quality performance category. If this measure were to be added to MIPS quality performance category, implementation of the measure would be delayed until the 2021 performance period for MIPS as explained in section III.I.3.B.(1)(ii). If the MCC measure were to be included in the MIPS quality performance category, we would also consider including the MIPS claims-based measures (MCC and MIPS All-Cause Readmission measure) in the MIPS APM scoring standard for ACOs in tracks (or payment models within a track) that are not Advanced APMs and in the MIPS quality performance category equivalent score for ACOs in tracks that are Advanced APMs, in order to fully align the quality scoring methodology under the Shared Savings Program with the MIPS scoring methodology to reduce the burden on ACOs and their eligible clinicians of tracking to multiple quality reporting requirements and quality scoring methodologies. We would then use this score for purposes of assessing quality performance under the Shared Savings Program for all ACOs. These MIPS claims-based measures are similar to those currently used to assess ACO quality under the Shared Savings Program. The proposed MIPS MCC and ACO MCC are similar because they both target patients with multiple chronic conditions but the cohort, outcome, and risk model for the proposed MIPS MCC measure would vary from the ACO MCC measure. The cohort for the ACO MCC includes eight conditions whereas the MIPS MCC measure includes nine conditions, where the additional condition is diabetes. The ACO MCC measure does not adjust for social risk factors whereas the MIPS MCC measure adjusts for two area-level social risk factors: (1) AHRQ socioeconomic status (SES) index; and (2) specialist density. For more detailed information on the MIPS MCC measure please refer to Appendix 1 Table AA (New Quality Measures Proposed for Addition for the 2023 Payment Year and Future Years) of this proposed rule. Both the MIPS and Shared Savings Program versions of the All-Cause Readmission measure were developed to fully align with the original hospital measure of Hospital-Wide Readmission. The MIPS and Shared Savings Program versions of the All Cause Readmission measure are essentially re-specifications of the same hospital measure and are updated annually to maintain that alignment. Because of this, the measures have a very similar, or identical, definition for included patients, outcome definition, and risk adjustment model. The primary

difference among the measures is only the entity that is accountable—either an ACO or a MIPS-eligible clinician—but the specifications are otherwise aligned. We also welcome comment on potentially including all of the MIPS claims-based measures in the MIPS quality performance category score for ACOs (instead of the 3 claims-based measures that are currently included in the Shared Savings Program quality score), and using this score (converted to a percentage of points earned out of the total points available) in place of the current Shared Savings Program quality score to assess quality performance for all ACOs for purposes of the Shared Savings Program. We note that we would also continue to assess ACOs on the CAHPS for ACOs survey but quality performance would be calculated by MIPS based on the methodology used for scoring the CAHPS for MIPS survey and included in the MIPS quality performance category score. The scoring and benchmarking approach for the CAHPS for MIPS is to assign points based on each summary survey measure (SSM) and then average the points for all the scored SSMs to calculate the overall CAHPS score. In contrast, ACOs currently, receive up to 2 points for each of the 10 SSMs for a total of 20 points.

In addition, we are soliciting comment on determining the threshold for minimum attainment in the Shared Savings Program using the MIPS APM quality performance category scoring. As noted previously in this section, ACOs in the first performance year of their first agreement period are considered to have met the quality performance standard and therefore to be eligible to share in savings or minimize shared losses, if applicable, when they completely and accurately report all quality measures. ACOs in all other performance years are required to completely and accurately report and meet the minimum attainment level on at least one measure in each domain, to be determined to have met the quality performance standard and to be eligible to share in savings. For these ACOs, minimum attainment is defined as a score that is at or above 30 percent or the 30th percentile of the performance benchmark. The 30th percentile for the Shared Savings Program is the equivalent of the 4th decile performance benchmark under MIPS APM quality performance category scoring. As we look to more closely align with MIPS quality performance category scoring in future years, we are considering how to determine whether ACOs have met the minimum attainment level. For example, minimum attainment could continue to be defined as complete and accurate reporting for ACOs in their first performance year of their first agreement period, while a MIPS quality performance category score that is at or above the 4th decile across all MIPS quality performance category scores would be required for ACOs in all other performance years under the Shared Savings Program. ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would not meet the quality performance standard for the Shared Savings Program and thus would not be eligible to share in savings or would owe the maximum shared losses, if applicable. In addition, ACOs with quality scores under the 4th decile of all MIPS quality performance category scores would be subject to compliance actions and possible termination. We recognize that a requirement that ACOs achieve an overall MIPS quality performance category score (or equivalent score) that meets or exceeds the 4th decile across all MIPS quality performance category scores is a higher standard than the current requirement that ACOs meet the 30th percentile on one measure per Shared Savings Program quality domain; however, section 1899(b)(3)(C) of the Act not only gives us discretion to establish quality performance standards for the Shared Savings Program, but also indicates that we should seek to improve the quality of care furnished by ACOs over time by specifying higher standards. We believe that increasing the minimum attainment level would incentivize improvement in the quality of care provided to the beneficiaries assigned to an ACO. Furthermore, consistent with section 1899(b)(3)(C) of the Act, it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. Given the maturity of the Shared Savings Program, we are also considering setting a higher threshold, such as the median or mean quality performance category score across all MIPS quality category scores, for determining eligibility to share in savings under the Shared Savings Program for all ACOs, other than those ACOs in their first performance year of their first agreement period. We welcome comment on these potential approaches or other approaches for determining Shared Savings Program quality minimum attainment using MIPS data.

We are also seeking comment on how to potentially utilize the MIPS quality performance category score to adjust shared savings and shared losses under the Shared Savings Program, as applicable. Currently, for all Shared Savings Program ACOs and Track 1+ Model ACOs, the ACO's quality score is multiplied with the maximum sharing rate of the track to determine the final sharing rate and therefore the amount of shared savings, if applicable. For some ACOs under two-sided models, specifically ACOs in Track 2 and the ENHANCED track, the ACO's quality score is also used in determining the amount of shared losses owed, if applicable. Under Track 2 and the ENHANCED track, the loss sharing rate is determined as 1 minus the ACO's final sharing rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively. Under the Track 1+ Model and two-sided models of the BASIC track (Levels C, D and E), the amount of shared losses is determined based on a fixed 30 percent loss sharing rate, regardless of the ACO's quality score. Thus, a higher quality score results in the ACO receiving a higher proportion of shared savings in all Shared Savings Program tracks and the Track 1+ Model, or greater mitigation of shared losses in Track 2 and the ENHANCED track. We could apply the MIPS quality performance category score to determine ACOs' shared savings and shared losses, if applicable, in the same manner. For instance, as an alternative to the current approach to determining shared savings payments for Shared Savings Program ACOs, we could establish a minimum attainment threshold, such as a score at or above the 4th decile of all MIPS quality performance category scores or the median or mean quality performance category score, that if met would allow ACOs to share in savings based on the full sharing rate of their track. We welcome comment on these or other potential approaches for utilizing the MIPS quality performance category score or an alternative score in determining shared savings or shared losses under the Shared Savings Program.

In addition, we are considering an option under which we would determine the MIPS quality performance category score for all Shared Savings Program ACOs as it is currently calculated for non-ACO group reporters using the CMS Web Interface. That is, ACOs would receive a score for each of the measures they report and zero points for those measures they do not report. This would be a change from the current methodology under which ACOs must report all Web Interface measures to complete quality reporting. We note that currently, for ACOs in the first year of their first agreement period,

minimum attainment is set at the level of complete and accurate reporting of all measures. If we were to adopt the MIPS quality performance category score as the Shared Savings Program quality score, we would consider no longer imposing a different quality standard for ACOs in the first year of their first participation agreement versus ACOs in later performance years. Given that the Shared Savings Program is evolving and many Medicare quality programs including MIPS are incentivizing performance rather than reporting, we are considering no longer transitioning from pay-for-reporting to pay-for-performance during an ACO's first agreement period in the Shared Savings Program. We believe that requiring all ACOs regardless of time in the program to be assessed on quality performance would be an appropriate policy since nearly 100 percent of ACOs consistently satisfactorily report all quality measures. We welcome comment on this alternative for determining the MIPS quality performance category score.

Lastly, we are seeking comment on using the MIPS quality improvement scoring methodology rather than the Shared Savings Program Quality Improvement Reward to reward ACOs for quality improvement. Under the Shared Savings Program, we currently allow ACOs not in their first performance year in the program to earn a Quality Improvement Reward in each of the four quality domains. In contrast, under MIPS improvement points are generally awarded as part of the MIPS quality performance category score if a MIPS eligible clinician (1) has a quality performance category achievement percent score for the previous performance period and the current performance period; (2) fully participates in the quality performance category for the current performance period; and (3) submits data under the same identifier for the 2 consecutive performance periods. If we were to adopt the MIPS quality performance category score for the Shared Savings Program quality score, quality improvement points earned under MIPS would be included in that score, and we would not have a need to add additional points to it. We welcome public comment on this or other approaches to considering improvement as part of using the MIPS quality performance category or an equivalent score, to determine quality performance under the Shared Savings Program.

We are seeking stakeholder feedback on the approaches discussed in this section of the proposed rule and any other recommendations regarding the potential alignment of the Shared Savings Program quality performance standard with the MIPS quality performance category in the assessment of ACO quality performance in the future for purposes of the Shared Savings Program.

2. Technical Change To Correct Reference in SNF–3 Day Rule Waiver Provision

In the December 2018 final rule, we made a number of amendments to § 425.612 (83 FR 68080). As part of these amendments, we redesignated paragraphs (a)(1)(v)(A) through (C) of § 425.612 as paragraphs (a)(1)(v)(C) through (E). In making these amendments, we inadvertently omitted a necessary update to a cross-reference to one of these provisions. Accordingly, we propose to remove the phase ''paragraph (a)(1)(v)(B)'' from § 425.612(a)(1)(v)(E), and in its place add the phrase ''paragraph (a)(1)(v)(D).''

F. Open Payments

1. Background

a. Open Payments Policies

The Open Payments program is a statutorily-mandated program that promotes transparency by providing information about the financial relationships between the pharmaceutical and medical device industry and certain types of health care providers and makes the information available to the public. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers'') to annually submit information for the preceding calendar year about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians and teaching hospitals.

Payments or other transfers of value that must be reported include such things as research, honoraria, gifts, travel expenses, meals, grants, and other compensation. The type of information required to be reported includes, but is not limited to, the date and amount of the payment or other transfer of value, identifying information about the covered recipient, and details about products associated with the transaction. When a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of that covered drug, device, biological or medical supply also must be reported under section 1128G of the Act. The estimated burden of these reporting requirements, as outlined under OMB control number 0938–1237, is just over 1 million hours over the course of 1 year.

Section 1128G of the Act establishes certain minimum dollar thresholds for required reporting, with two bases for reporting, individual and aggregate payments or transfers of value. To determine if small individual payments or other transfers of value made to a covered recipient exceed the aggregate threshold and must be reported, applicable manufacturers and applicable GPOs must aggregate all individual payments made across all payment categories within a given reporting year. The statutory threshold established in 2013 was $10 for individual payments, and $100 for aggregated payments, and this amount has increased with the consumer price index each year. For CY 2019, the annual reporting thresholds for individual payments or other transfers of value is $10.79 and the aggregate amount is $107.91.

The Open Payments program yields transparency that provides information to the general public that may influence their health care decision-making and choice of providers, as well as information that researchers looking into potential correlations between financial relationships and provider behaviors may use. More than 51 million records have been disclosed under the Open Payments program since August 2013, enabling significant transparency into covered exchanges of value. We have been committed to stakeholder engagement in an effort to limit burden in the Open Payments program reporting processes and improve clarity for the public. Additional background about the program and guidance, including FAQs, about how the program works and what type of information is required to be reported is available at *www.cms.gov/OpenPayments*.

In the February 8, 2013 **Federal Register** (78 FR 9458), we issued regulations implementing section 1128G of the Act to create the Open Payments program. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers'') to submit information annually about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians and teaching hospitals, during the course of the preceding calendar year. Additionally, section 1128G of the Act defines covered drugs, devices, biologicals, or medical supplies as those covered under Medicare or a State plan under Medicaid or the CHIP

(or a waiver of such a plan); and requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or physician's immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Under section 1128G(e)(10)(A) of the Act, the term ''payment or other transfer of value'' refers to a transfer of anything of value, though some exclusions apply.

In the CY 2015 PFS final rule with comment period (79 FR 67548), we revised the regulations by standardizing reporting in the Open Payments program. Specifically, we: (1) Deleted the definition of ''covered device''; (2) removed the special rules for payments or other transfers of value related to continuing education programs; (3) clarified the marketed name reporting requirements for devices and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

In the CY 2017 PFS proposed rule (81 FR 46395), we solicited information from the public on a wide variety of information regarding the Open Payments program. Since the implementation of the program and changes made in the CY 2015 PFS final rule with comment period, various commenters have provided us feedback. Consequently, we identified areas in the rule that might benefit from revision and solicited public comments to inform future rulemaking. We sought comment on whether the nature of payment categories listed at § 403.904(e)(2) are adequately inclusive to facilitate reporting of all payments or transfers of value, and sought ways to streamline or make the reporting process more efficient while facilitating our role in oversight, compliance, and enforcement, along with posing other program-specific questions. A summary of solicited comments was published in the CY 2017 PFS final rule (81 FR 80428–80429).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–270) was signed into law. Section 6111 of the SUPPORT Act amended the definition of ''covered recipient'' under section 1128G(e)(6) of the Act with respect to information required to be submitted on or after January 1, 2022, to include physician assistants (PA), nurse practitioners (NP), clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM), in addition to the previously listed covered recipients of physicians and teaching hospitals. This rule proposes to codify the Open Payments provisions from the SUPPORT Act, proposes to address public comments received from the CY 2017 PFS proposed rule by simplifying the process for reporting data by adjusting the nature of payment categories, and proposes changes to standardize data on reported covered drugs, devices, biologicals, or medical supplies.

b. Legal Authority

Three principal legal authorities from the Social Security Act ground our proposed provisions:

- Sections 1102 and 1871, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1861, which defines providers and suppliers.
- Section 1128G, as amended by section 6111 of the SUPPORT Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals, and to PAs, NPs, CNSs, CRNAs, and CNMs for information required to be submitted under section 1128G of the Act on or after January 1, 2022.

c. Proposed Changes

In this rule, we propose to revise several Open Payments regulations at 42 CFR part 403. We are proposing that the following provisions be effective for data collected beginning in CY 2021 and reported in CY 2022: (1) Expanding the definition of a covered recipient to include the categories specified in the SUPPORT Act; (2) expanding the nature of payment categories; and (3) standardizing data on reported covered drugs, devices, biologicals, or medical supplies. We are also proposing a correction to the national drug codes (NDCs) reporting requirements for drugs and biologicals that, should the rule be finalized as proposed, would be effective 60 days following the publication of the final rule. We believe this would give all stakeholders sufficient time to prepare for these requirements.

(1) Expanding the Definition of a Covered Recipient

Section 1128G of the Act requires applicable manufacturers and applicable GPOs to report annually information about certain payments or other transfers of value made to covered recipients, as well as ownership or investment interests held by physicians or their immediate family members in such entities, though at section 1128G(e)(7) of the Act it excepts physicians who are employed by the reporting manufacturer, such that manufacturers do not report payments to their own employees. As we noted previously, section 6111 of the SUPPORT Act expanded the definition of covered recipients from physicians and teaching hospitals to include PAs, NPs, CNSs, CRNAs, and CNMs; it likewise expanded to these individuals the same exception for manufacturer-employment. The SUPPORT Act requires these changes to be in effect for information required to be submitted on or after January 1, 2022. In short, applicable manufacturers will be required to report transfers of value pertaining to these additional provider types in the same way they have been required to report transfers of value to physicians and teaching hospitals. Since the information is reported to CMS in the calendar year following the year in which it was collected, this means that the data would be collected by the industry during CY 2021.

We are proposing to revise § 403.902 to align with the statutory requirements in sections 1128G(e)(6)(A) and (B) of the Act. Specifically, we are proposing to revise the definition of ''covered recipient'' in § 403.902 to include PAs, NPs, CNSs, CRNAs, and CNMs. In addition, we are proposing at § 403.902 to reference the definitions of these additional provider types as defined in sections 1861(aa)(5)(A), 1861(aa)(5)(B), 1861(bb)(2), and 1861(gg)(2) of the Act.

We are also proposing to update certain provisions in part 403, subpart I to include provider and supplier types other than physicians as specified in sections 1128G(e)(6)(A) and (B) of the Act. Specifically, we propose the following revisions:

- In § 403.902, to add the definitions of ''certified nurse midwife,'' ''certified registered nurse anesthetist,'' ''clinical nurse specialist,'' ''non-teaching hospital covered recipient,'' ''nurse practitioner,'' and ''physician assistant.''
- In § 403.902, to revise the definition of ''covered recipient'' by adding physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife'' after the phrase ''Any physician.''
- In § 403.904(c)(1), (f)(1)(i)(A), and (h)(7), to replace the term ''physician''

with the phrase ''non-teaching hospital.''

• In § 403.904(c)(3), to replace the term ''physician'' in the title with the phrase ''non-teaching hospital,'' add the phrase ''non-teaching hospital'' after ''In the case of a,'' and remove the phrase ''who is a physician'' from the text.

• In § 403.904(c)(3)(ii) and (iii), (f)(1)(i)(A)(*1*), (f)(1)(i)(A)(*3*) and (*5*), and (f)(1)(v), to change the term ''physician'' to the phrase ''non-teaching hospital covered recipient.''

• In § 403.904(h)(13), to remove the phrase ''who is a physician'' and add the phrase ''non-teaching hospital'' after ''In the case of.''

• In § 403.904(f)(1), to remove the phrase ''(either physicians or teaching hospitals).''

• In § 403.908(g)(2)(ii), to change the words ''physicians and teaching hospitals'' to the term ''Covered recipients.''

(2) Nature of Payment Categories

Applicable manufacturers and applicable GPOs must characterize the nature of payments made to covered recipients by selecting the ''Nature of Payment'' category that most closely describes the reported payment. Some of the ''Nature of Payment'' categories, as specified at § 403.904(e)(2), are specifically required by section 1128G(a)(1)(A)(vi) of the Act, while the statute also allows the Secretary to define any other nature of payment or other transfer of value.

Based upon information we obtained from the public comments solicited in the CY 2017 PFS proposed rule (81 FR 46395), stakeholders have identified debt forgiveness, long term medical supply or device loan, and acquisitions (among others) as useful categories to add to comply with the general reporting requirement under section 1128G(a)(1)(A) of the Act. Therefore, and so as to add clarity to the types of payments or transfers of value made by applicable manufactures and applicable GPOs to covered recipients, we are proposing to revise the ''Nature of Payment'' categories in § 403.904(e)(2) by consolidating two duplicative categories and by adding the three new categories described below.

First, the categories that we are proposing to consolidate include two separate categories for continuing education programs. Section 1128G(a)(1)(A)(vi)(XIII) of the Act requires manufacturers to report direct compensation for serving as faculty or a speaker for medical education programs. The current § 403.904(e)(2)(xiv) and (xv) distinguish between accredited/certified and unaccredited/non-certified continuing education programs. At proposed revised § 403.904(e)(2)(xv), we are proposing to consolidate these categories and make the regulatory wording match the statutory language ''medical education programs,'' which we believe would streamline the reporting requirements while not detracting from the underlying context of the data. Although we defined separate categories at the inception of the Open Payments program, we no longer believe that the distinction in this category is necessary.

In addition, we are proposing three additional categories that would operate prospectively and would *not* require the updating of previously reported payments or other transfers of value that may fall within these new categories.

The three new categories are as follows:

• *Debt Forgiveness* (proposed § 403.904(e)(2)(xi)): This would be used to categorize transfers of value related to forgiving the debt of a covered recipient, a physician owner, or the immediate family of the physician who holds an ownership or investment interest.

• *Long-Term Medical Supply or Device Loan* (proposed new § 403.904(e)(2)(xiv)): Section 403.904 currently contains an exclusion from reporting for the loan of a covered device, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days, or a quantity of 90 days of average use, respectively. This new category would be used to characterize the loans of covered devices or medical supplies for longer than 90 days. (*Note:* We are proposing to combine current paragraphs on continuing education programs § 403.904(e)(2)(xiv) and (xv) to replace paragraph (e)(2)(xv) as noted in the consolidating continuing education programs above.)

• *Acquisitions* (proposed § 403.904(e)(2)(xviii)): This addition would provide a category for characterizing buyout payments made to covered recipients in relation to the acquisition of a company in which the covered recipient has an ownership interest.

We also are proposing to add the definition of ''long-term medical supply or device loan'' to § 403.902 as ''the loan of supplies or a device for 91 days or longer.'' For consistency within the definitions section, we propose to redesignate § 403.904(h)(5)—which contains the definition of ''short-term medical supply or device loan'' to § 403.902. As a result, we are proposing a new § 403.904(h)(5) to be ''short-term medical supply or device loan.''

(3) Standardizing Data on Reported Covered Drugs, Devices, Biologicals, or Medical Supplies

When applicable manufacturers or applicable GPOs report payments or transfers of value related to specific drugs and biologicals, we currently require names and NDCs to be reported to the Open Payments program. However, based upon the lack of federally-recognized identifiers when we started the Open Payments program, we have not required analogous reporting for medical devices from the manufacturers. However, the Food and Drug Administration (FDA) established and continues to implement a system for the use of standardized unique device identifiers (UDIs) for medical devices and has issued regulations at 21 CFR part 801, subpart B, and 21 CFR part 830, requiring, among other things, that a UDI be included on the label of most devices distributed in the United States. (See 78 FR 58785, September 24, 2013.) Based upon the FDA's UDI regulatory requirements and the HHS Office of the National Coordinator's requirement that UDIs form part of the Common Clinical Data Set (45 CFR part 170), we believe that the use of UDIs and device identifiers (DIs), a subcomponent of the UDI, have become more standardized. Moreover, the HHS Office of Inspector General (OIG) included a recommendation for Open Payments to require more specific information about devices in an August 2018 report (OEI–03–15–00220).

With the standardization and typical use of UDIs and based upon OIG's recommendation, we propose that the DI component, the mandatory fixed portion of the UDI assigned to a device, if any, should be incorporated into Open Payments reporting that applicable manufacturers or applicable GPOs provide. We do not propose to require a full UDI. We believe such a step would substantially aid in enhancing the quality of the Open Payments data because the identifiers can be used to validate submitted device information. This effort would also enhance the usefulness of Open Payments data to the public by providing more precise information about the medical supplies and devices associated with a transaction. Specifically, we are proposing to revise § 403.904(c)(8) to require applicable manufacturers and applicable GPOs to provide the DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly.

We also seek to further clarify the reporting requirements with regard to drugs and biologicals. Since the outset of the Open Payments program, NDCs have been required for both research and non-research payments. In § 403.904(f)(1)(iv), we require that NDCs be reported for drugs and biologicals used in research. However, in the CY 2015 PFS final rule with comment period (79 FR 67548), the non-research payment NDC requirement was erroneously removed when changes were made to the rule text regarding marketed names. We propose to correct this error in order to reiterate that NDCs are required for both research and non-research payments and to make the change effective 60 days from publishing the final rule.

We propose to revise § 403.904(c)(8) to require DIs (if any) to identify reported devices in a comprehensive fashion meaningful to the users of Open Payments data and reorganize the section accordingly. We also propose to reincorporate language that specifically requires reporting of NDCs.

As a result of the proposed changes to § 403.904(c)(8), we are also proposing technical changes to § 403.904(f)(1)(iv) and to add mirrored definitions from 21 CFR 801.3 for ''device identifier'' and ''unique device identifier'' to § 403.902.

G. Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy

Section 5012 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255; enacted December 13, 2016) created a separate Medicare Part B benefit under section 1861(s)(2)(GG) and section 1861(iii) of the Act to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment in the beneficiary's home, effective for January 1, 2021. Section 5012 of the Cures Act also added section 1834(u) to the Act that establishes the payment and related requirements for home infusion therapy under this benefit.

Specifically, section 1834(u)(6) of the Act requires that prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) of the Act for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy treatment options. For example, a physician may verbally discuss the treatment options with the patient during the visit and annotate the treatment decision in the medical records before establishing the infusion plan. Some physicians may also provide options in writing to the patient in the hospital discharge papers or office visit summaries, as well as retain a written patient attestation that all options were provided and considered. The frequency of discussing these options could vary based on a routine scheduled visit or according to the individual's clinical needs.

We are soliciting comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B as required under section 1834(u)(6) of the Act. We also invite comments on any additional interpretations of this notification requirement.

H. Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

1. Enrollment of Opioid Treatment Programs

a. Legislative and Regulatory Background

As previously explained in more detail in this proposed rule, the SUPPORT Act was designed to alleviate the nationwide opioid crisis by: (1) Reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions to the crisis. The SUPPORT Act attempts to fulfill these objectives, in part, by establishing a new Medicare benefit category for opioid treatment programs (OTPs) pursuant to section 2005 thereof. Section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) classifying OTPs as Medicare providers (though only with respect to the furnishing of opioid use disorder treatment services). This will enable OTPs that meet all applicable statutory and regulatory requirements to bill and receive payment under the Medicare program for furnishing such services to Medicare beneficiaries.

b. Definition of and Certain Requirements for OTPs

As already mentioned, an OTP is currently defined in 42 CFR 8.2 as a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1). Section 2005(b) of the SUPPORT Act added a new section 1861(jjj)(2) to the Act defining an OTP as an entity that meets, among other things, the definition of an OTP in § 8.2 (or any successor regulation). Section 1861(jjj)(2) of the Act also outlines certain additional requirements that an OTP must meet to qualify as such. These requirements include the following:

(1) Accreditation

Consistent with new section 1861(jjj)(2)(C) of the Act, as added by section 2005(b) of the SUPPORT Act, and also required under 42 CFR 8.11(a)(2), an OTP must have a current, valid accreditation by an accrediting body or other entity approved by the SAMHSA, the federal agency that oversees OTPs. A core purpose of OTP accreditation is to ensure that an OTP meets: (1) Certain minimum requirements for furnishing medication-assisted treatment (MAT); and (2) the applicable accreditation standards of SAMHSA-approved accrediting bodies, of which there presently are six. The accreditation process includes, but is not limited to, an accreditation survey, which involves an onsite review and evaluation of an OTP to determine compliance with applicable federal standards.

(2) Certification

A second requirement addressed in section 1861(jjj)(2)(B) of the Act, as added by section 2005(b) of the SUPPORT Act, is also in current regulations referenced in 42 CFR 8.11(a). Along with accreditation, an OTP must have a current, valid certification by SAMHSA for such a program. The prerequisites for certification (as well as the certification process itself) are outlined in 42 CFR 8.11 and include, but are not restricted to, the following:

- Current and valid accreditation (as described previously);
- Adherence to the federal opioid treatment standards described in § 8.12;
- Compliance with all pertinent state laws and regulations, as stated in § 8.11(f)(1);
- Per § 8.11(f)(6), compliance with all regulations enforced by the Drug Enforcement Administration (DEA)

under 21 CFR chapter II; this includes registration by the DEA before administering or dispensing opioid agonist treatment medications; and

• As stated in § 8.11(a)(2), compliance with all other conditions for certification established by SAMHSA.

Under § 8.11(a)(3), certification is generally for a maximum 3-year period, though this may be extended by 1 year if an application for accreditation is pending. SAMHSA may revoke or suspend an OTP's certification if any of the applicable grounds identified in § 8.14(a) or (b), respectively, exist. Under § 8.11(e)(1), an OTP that has no current certification from SAMHSA but has applied for accreditation with an accreditation body may obtain a provisional certification for up to 1 year.

At the time of application for certification or any time thereafter, an OTP may request from SAMHSA an exemption from the regulatory requirements of §§ 8.11 and 8.12. Section 8.11(h), which governs the exemption process, cites an example of a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible; he or she may choose to seek an exemption from some of the staffing and service standards.

According to SAMHSA statistics, there are currently about 1,677 active OTPs; of these, approximately 1,585 have full certifications and 92 have provisional certifications.

(3) OTP Enrollment

Most pertinent to the discussion and proposals below, section 2005(b) of the SUPPORT Act, which added a new section 1861(jjj)(2)(A) to the Act, requires that an OTP be enrolled in the Medicare program under section 1866(j) of the Act to qualify as an OTP and to bill and receive payment from Medicare for opioid use disorder treatment services. Per section 1861(jjj)(2)(A) of the Act, the provisions of this proposed rule would establish requirements that OTPs must meet in order to enroll in Medicare.

c. Current Medicare Enrollment Process

(1) Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. As further explained below, CMS and its Medicare Administrative Contractors (MACs; hereafter occasionally referred to as ''contractors'') carefully and closely screen and review Medicare enrollment applicants to verify that they meet all applicable legal requirements.

CMS has taken various steps via regulation to outline a process for enrolling providers and suppliers in the Medicare program. In the April 21, 2006 **Federal Register** (71 FR 20754), we published the ''Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment'' final rule that set forth certain requirements in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570) that providers and suppliers must meet to obtain and maintain Medicare billing privileges. In the April 21, 2006 final rule, we cited sections 1102 and 1871 of the Act as general authority for our establishment of these requirements, which were designed for the efficient administration of the Medicare program.

Subsequent to the April 21, 2006 final rule, we published additional provider enrollment regulations. These were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items.

One of the provider enrollment regulations was the ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers'' final rule published in the February 2, 2011 **Federal Register** (76 FR 5862). This final rule implemented various provisions of the Affordable Care Act, including the following:

• Added a new § 424.514 that required submission of application fees by institutional providers (as that term is defined in § 424.502) as part of the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) provider enrollment processes.

• Added a new § 424.518 that established Medicare, Medicaid, and CHIP provider enrollment screening categories and requirements based on the CMS-assessed level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier.

We also published the ''Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment'' final rule in the December 5, 2014 **Federal Register** (79 FR 72499) wherein we addressed several vulnerabilities in the provider enrollment process. As part of the December 2014 final rule—

• We expanded the number of reasons for which we can: (1) deny a prospective provider's or supplier's enrollment in the Medicare program under § 424.530; or (2) revoke the Medicare enrollment of an existing provider or supplier under § 424.535.

• We supplemented the existing denial reason in § 424.530(a)(3) such that we could deny a prospective provider's or supplier's Medicare enrollment if a managing employee (as that term is defined in § 424.502) of the provider or supplier has, within the 10 years preceding enrollment or revalidation of enrollment, been convicted of a federal or state felony offense that we determined to be detrimental to the best interests of the Medicare program and its beneficiaries.

• We expanded the existing revocation reason in § 424.535(a)(8) to allow us to revoke a provider's or supplier's enrollment if we determine that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.

In addition to these final rules, we have also made several other regulatory changes to 42 CFR part 424, subpart P to address various program integrity issues that have arisen.

(2) Form CMS–855—Medicare Enrollment Application

Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System) captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare

requirements. Data collected on the Form CMS–855 is carefully reviewed and verified by CMS or its MACs and includes, but is not limited to:

- General identifying information (for example, legal business name, tax identification number).
- Licensure and/or certification data.
- Any final adverse actions (as that term is defined in § 424.502) of the provider or supplier, such as felony convictions, exclusions by the HHS Office of Inspector General (OIG), or state license suspensions or revocations.
- Practice locations and other applicable addresses of the provider or supplier.
- Information regarding the provider's or supplier's owning and managing individuals and organizations and any final adverse actions those parties may have.
- As applicable, information about the provider's or supplier's use of a billing agency.

The Form CMS–855 application is used for a number of provider enrollment transactions, such as:

- Initial enrollment: The provider or supplier is enrolling in Medicare for the first time, enrolling in another MAC's jurisdiction, or seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership: The provider or supplier is reporting a change in its ownership.
- Revalidation: The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515.
- Reactivation: The provider or supplier is seeking to reactivate its Medicare billing privileges after being deactivated under § 424.540.
- Change of information: The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving a provider's or supplier's initial enrollment application, reviewing and confirming the information thereon, and determining whether the provider or supplier meets all applicable Medicare requirements, CMS or the MAC will either: (1) Approve the application and grant billing privileges to the provider or supplier (or, depending upon the provider or supplier type involved, simply recommend approval of the application and refer it to the state agency or to the CMS regional office, as applicable); or (2) deny enrollment under § 424.530.

d. Proposed OTP Enrollment Provisions

(1) Legal Basis and Necessity

As mentioned earlier, section 1861(jjj)(2)(A) of the Act requires OTPs to enroll in Medicare to bill and receive payment. In the proposals discussed in this section III.I.3. of this proposed rule, we outline the proposed requirements and procedures with which OTPs must comply to enroll and remain enrolled in Medicare. In doing so, we are relying on the authority granted to us not only under section 1861(jjj)(2)(A) of the Act but also under several other statutory provisions. First, section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Second, sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

We believe, and it has been our longstanding experience, that the provider enrollment process is invaluable in helping to ensure that: (1) All potential providers and suppliers are carefully screened for compliance with all applicable requirements; (2) problematic providers and suppliers are kept out of Medicare; and (3) beneficiaries are protected from unqualified providers and suppliers. Indeed, without this process, the Medicare program and Medicare beneficiaries are endangered, and billions of Trust Fund dollars may be paid to unqualified or fraudulent parties.

Nor, we add, are our general concerns restricted to the mere need and desire to establish provider enrollment requirements for OTPs. Though a very critical one, provider enrollment is only a single component of CMS' much broader program integrity efforts. We emphasize that in establishing and implementing an overall Medicare OTP process per the SUPPORT Act and implementing an overall program integrity strategy, our objectives will extend to matters such as: (1) Monitoring OTP billing patterns; (2) ensuring the proper payment of OTP claims; (3) performing OTP audits as required by law; (4) making certain that OTP beneficiaries receive quality care; and (5) taking action (enrollment-related or otherwise) against non-compliant or abusive OTP providers. In other words, it should not be assumed for purposes of the OTP process that the term ''program integrity'' is limited to the provider enrollment concept, for it actually applies to many other types of payment safeguards as well.

(2) OTP Enrollment Requirements

(a) Addition of 42 CFR 424.67 and General OTP Requirement To Enroll

We propose to establish a new 42 CFR 424.67 that would include most of our proposed OTP provisions. In paragraph (a), we are proposing that in order for a program to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2) and enroll in the Medicare program under the provisions of subpart P of this part and this section. As previously indicated, subpart P outlines the requirements and procedures of the enrollment process. All providers and suppliers that seek to bill Medicare must enroll in Medicare and adhere to all enrollment requirements in subpart P. Proposed § 424.67 would implement the above-mentioned requirement stated in section 1861(jjj)(2)(A) of the Act.

(b) OTPs—Procedures and Compliance

In paragraph (b) of § 424.67, we are proposing several specific enrollment requirements that OTPs must meet that either clarify or supplement those contained in subpart P.

(i) OTPs: Form CMS–855B

In § 424.67(b)(1), we propose that an OTP must complete in full and submit the Form CMS–855B application (''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'') (OMB Control No.: 0938–0685) and any applicable supplement or attachment thereto (which would be submitted to OMB under control number 0938–0685) to its applicable Medicare contractor. While we recognize that the Form CMS–855B is typically completed by suppliers rather than providers, we believe that certain unique characteristics of OTPs (for example, OTPs would only bill Medicare Part B) make the Form CMS–855B the most suitable enrollment application for OTPs. The supplement or attachment would capture certain information that is: (1) Unique to OTPs but not obtained via the Form CMS–855B; and (2) necessary to enable CMS to effectively screen their applications and confirm their qualifications.

As part of this general requirement concerning CMS–855 form completion, we propose two subsidiary requirements as part of the aforementioned supplement/attachment.

First, in § 424.67(b)(1)(i), we propose that the OTP must maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians and other eligible professionals (as the

term ''eligible professional'' is defined in section 1848(k)(3)(B) of the Act) who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's or other eligible professional's first and last name and middle initial, Social Security Number, National Provider Identifier, and (4) license number (if applicable). This requirement, in our view, would enable us to: (1) Confirm that these individuals are qualified to perform the activities in question; and (2) screen their prescribing practices, the latter being an especially important consideration in light of the nationwide opioid epidemic.

Second, we propose in § 424.67(b)(1)(ii) that the OTP must certify via the Form CMS–855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in § 424.67(b) and (d) (discussed below). This is to help ensure that the OTP fully understands its obligation to maintain constant compliance with the requirements associated with OTP enrollment.

We do not believe that the requirements addressed in proposed § 424.67(b)(1) duplicate any other information collection effort involving OTPs. Indeed, the OTP enrollment process will capture various data elements not collected via other means, such as the SAMHSA certification process. Such data elements include the name, social security number (SSN) and National Provider Identification (NPI) number of all eligible professionals at the OTP who are legally authorized to prescribe, order, or dispense controlled substances. While SAMHSA's approved accreditation bodies do verify that these individuals have appropriate licensure, they do not collect this information on a form, screen against federal databases, or have a database that keeps this information. CMS, however, intends to conduct these activities.

(ii) OTPs: Application Fee

As mentioned previously in our discussion of the February 2, 2011 final rule, under § 424.514, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the applicable application fee. (For CY 2019, the fee amount is $586.) Section 424.502 defines an institutional provider as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations, which are exempt from the fee requirement if they are enrolling as a physician or non-physician practitioner organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application. Since an OTP, as a specialized facility, would be required to complete the Form CMS–855B to enroll in Medicare as an OTP (and would not be enrolling as a physician and non-physician organization), we believe that an OTP would meet the definition of an institutional provider under § 424.502. It would therefore be required to pay an application fee consistent with § 424.514; we are proposing to clarify this requirement to pay the fee in new § 424.67(b)(2).

(c) OTPs: Categorical Risk Designation

We previously referenced § 424.518, which outlines screening categories and requirements based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the level of scrutiny with which CMS will screen and review providers or suppliers within that category.

There are three categories of screening in § 424.518: High, moderate, and limited. Irrespective of which category a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location:

- Verifies that a provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
- Conducts state license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

However, providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Furthermore, for those in the high categorical risk level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are intended to correspond to the heightened risk involved.

There currently are only three provider or supplier types that fall within the high categorical risk level under § 424.518(c)(1): Newly/initially enrolling home health agencies (HHAs); newly/initially enrolling suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and newly/initially enrolling Medicare Diabetes Prevention Program (MDPP) suppliers. We are now proposing to assign newly enrolling OTPs to the high categorical risk level.

A principal concern is that, as indicated previously, we have no historical information on OTPs (either from an enrollment, billing, or claims payment perspective) upon which we can fairly estimate the degree of risk they may pose. This is because OTP services are an entirely new Medicare benefit. We expressed similar concerns regarding our inclusion of MDPP suppliers in § 424.518(c)(1). That is, in the CY 2017 PFS proposed rule (81 FR 46162), we proposed to assign MDPP suppliers to the high categorical risk level because the MDPP could bring organization types that are entirely new to Medicare.

Our concerns about OTPs go well beyond the above-referenced lack of historical information, though. The opioid epidemic has, in our view, increased the potential for unscrupulous providers to take advantage of Medicare beneficiaries through fraudulent billing schemes and abusive prescribing practices; recent examples include ''patient brokers'' in Massachusetts, as well as excessive stays in ''sober homes'' in Florida. Furthermore, there is a heightened risk in OTP facilities compared to other types of providers due to: (1) The core service provided at the facilities—the prescribing and dispensing of methadone and other opioids as part of medication-assisted treatment for opioid addiction; and (2) the nature of the patients at the facilities, that is, individuals grappling with opioid addiction. By assigning OTPs to the ''high-risk'' screening level—thereby capturing fingerprints of all 5 percent or greater owners and conducting site visits—we would be taking a preventative approach to stopping fraudulent billing and prescribing practices and keeping Medicare beneficiaries safe.

Given the foregoing, we are proposing four regulatory provisions. First, we are

proposing to state in new § 424.67(b)(3) that newly enrolling OTP providers will be screened at the high categorical risk level in accordance with the requirements of § 424.518(c). Second, we are proposing to add a new paragraph (iv) to § 424.518(c)(1) that would add newly enrolling OTPs to the types of providers and suppliers screened at the high categorical risk level. Third, we are proposing to add a new paragraph (xii) to § 424.518(b)(1) whereby OTPs that are revalidating their current Medicare enrollment (under § 424.515) would be screened at the moderate categorical risk level (which involves a site visit but does not include the fingerprint submission requirement of the high categorical risk level). This would be consistent with our approach towards DMEPOS suppliers, HHAs, and MDPPs, which are screened at the high categorical risk level when newly enrolling and at the moderate level when revalidating. Fourth, and consistent with the addition of new § 424.518(b)(1)(xii), we propose to require that, upon revalidation, the OTP successfully complete the moderate categorical risk level screening required under § 424.518(b) in order to remain enrolled in Medicare. This provision would be designated as new § 424.67(d)(1)(iii); as discussed below, proposed paragraph (d) addresses ongoing obligations and standards with which enrolled OTPs must comply.

(d) OTPs: Certification

We are proposing in new § 424.67(b)(4) that to enroll in Medicare, an OTP must have in effect a current, valid certification by SAMHSA for such a program. This requirement is consistent with both section 1861(jjj)(2)(B) of the Act and § 8.11. We consider SAMHSA certification to be extremely important because it would: (1) Assist us in ensuring that the provider is qualified to furnish OTP services; and (2) help confirm that the provider is in compliance with the relevant provisions of part 8 and other applicable requirements (such as federal opioid treatment standards).

We noted earlier that, under § 8.11(e), OTPs with no current SAMHSA certification that have applied for accreditation with an accreditation body are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP must submit to SAMHSA certain information required under § 8.11(e), along with:

- A statement identifying the accreditation body to which the OTP has applied for accreditation;
- The date on which the OTP applied for accreditation;
- The dates of any accreditation surveys that have taken place or are expected to take place; and
- The expected schedule for completing the accreditation process.

Under proposed § 424.67(b)(4)(ii), we state that we would not accept a provisional certification under § 8.11(e) in lieu of the certification described in § 8.11(a). As already mentioned, section 1861(jjj)(2)(B) of the Act states that an OTP must have in effect a certification by SAMHSA, a requirement we interpret to mean full SAMHSA certification rather than provisional certification. Indeed, provisional certification under § 8.11(e) applies to OTPs that do not have a current SAMHSA certification but have applied for accreditation with an accreditation body. Section 1861(jjj)(2)(C) of the Act, however, requires actual accreditation rather than the mere application for accreditation. Thus, we believe that full certification should be required.

(e) OTPs: Managing Employees

Consistent with sections 1124 and 1124A of the Act, an enrolling provider or supplier must disclose all of its managing employees on the Form CMS–855 application. Section 424.502 of our regulations defines a managing employee as a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over (or who directly or indirectly conducts) the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier. We are proposing in new § 424.67(b)(5) that all of the OTP's staff that meet the regulatory definition of managing employee must be reported on the Form CMS–855 application and/or any applicable supplement. Such individuals would include, but not be limited to, the OTP's medical director and program sponsor (both as described in § 8.2).

(f) Standards Specific to OTPs

Given the previously mentioned concerns about the nationwide opioid crisis and the need for drugs to be prescribed and, moreover, dispensed, in a careful, reasonable manner, we believe that OTPs should adhere to certain standards unique to the services they provide. In particular, we wish to ensure that problematic providers and personnel are not prescribing or dispensing drugs on behalf of the OTP. To this end, we propose the following additional requirements with which OTPs must comply in order to enroll in Medicare.

In new § 424.67(b)(6)(i), we propose that an OTP must not employ or contract with a prescribing or ordering physician or other eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony that we deem detrimental to the best interests of the Medicare program and its beneficiaries, based on the same categories of detrimental felonies, as well as case-by-case detrimental determinations, found at 42 CFR 424.535(a)(3). This provision would apply irrespective of whether the individual in question is: (1) Currently dispensing narcotics at or on behalf of the OTP; or (2) a W–2 employee of the OTP. We note that SAMHSA recognizes the importance of dispensing personnel in an OTP's operations by requiring, as part of the certification process, disclosure of the names and state license numbers of all OTP personnel (other than program physicians) who legally dispense narcotic drugs even if they are not, at present, responsible for administering or dispensing methadone at the program. Such individuals include pharmacists, registered nurses, and licensed practical nurses. (See *https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs.apply*.) We, too, acknowledge the crucial roles of such persons in ensuring the safe dispensing of medicines and believe that those with felonious histories pose a potential risk to the health and safety of Medicare beneficiaries.

This overarching concern regarding possible patient harm also lies behind our proposed standards in new § 424.67(b)(6)(ii) and (iii). In the former paragraph, we propose that the OTP must not employ or contract with any personnel, regardless of whether the individual is a W–2 employee of the OTP, who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under §§ 422.222 or 423.120(c)(6). In § 424.67(b)(6)(iii), we propose that the OTP must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a current or prior adverse action imposed by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. We would consider the

factors enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this provision.

Concerning § 424.67(b)(6)(ii), we believe that OTP personnel who are revoked from Medicare for problematic behavior present a potential threat to the OTP's patients. We hold a similar view regarding persons on the preclusion list (as that term is defined in §§ 422.2 and 423.100). Indeed, such individuals are precluded from receiving payment for Medicare Advantage (MA) items and services or Part D drugs furnished or prescribed to Medicare beneficiaries under, respectively, §§ 422.222 or 423.120(c)(6), due to, in general, a prior felony conviction, a current revocation, or behavior that would warrant a revocation if the person were enrolled in Medicare. As for § 424.67(b)(6)(iii), we discuss in detail our proposed new revocation reason at § 424.535(a)(22) in section III.H.2. of this proposed rule. This proposed new revocation ground pertains to improper conduct that led to patient harm. In light of the aforementioned and critical need to preserve the safety of Medicare beneficiaries, we believe that § 424.67(b)(6)(iii) is an appropriate requirement.

(g) Provider Agreement

(i) General Requirement

As previously mentioned, section 2005(d) of the SUPPORT Act amended section 1866(e) of the Act by adding a new paragraph (3) classifying OTPs as Medicare providers, though only with respect to the furnishing of opioid use disorder treatment services. Under section 1866(a)(1) of the Act, all Medicare providers (as that term is defined in section 1866(e) of the Act) must enter into a provider agreement with the Secretary. Section 1866(a)(1) outlines required terms of the provider agreement, such as allowed charges for furnished services.

Consistent with these requirements, and as previously discussed in more detail in this proposed rule, we are proposing to revise various sections of 42 CFR part 489 to include OTPs within the category of providers that must sign a provider agreement in order to participate in Medicare. To incorporate this requirement into § 424.67 as a prerequisite for enrollment, we propose to state in new § 424.67(b)(7)(i) that an OTP must, in accordance with the provisions of 42 CFR part 489, sign (and adhere to the terms of) a provider agreement with CMS in order to participate and enroll in Medicare.

(ii) Appeals

Under § 489.53, we may terminate a provider agreement if any of the circumstances outlined in that section apply (for example, the provider under § 489.53(a)(1) fails to comply with the provisions of Title XVIII of the Act). The provider may, however, appeal any such termination pursuant to 42 CFR part 498. This process is akin to what occurs with Medicare revocations, whereby: (1) Medicare may revoke a provider's or supplier's Medicare enrollment for any of the reasons identified in § 424.535; and (2) the provider or supplier may appeal said revocation under part 498. There is, though, an additional important result of the revocation process; under § 424.535(b), when a provider's or supplier's billing privileges are revoked, any provider agreement in effect at the time of revocation is terminated effective with the date of revocation.

Given this linkage in § 424.535(b) between a revocation of enrollment and the termination of a provider agreement, we are concerned about the potential for duplicate appeals processes (that is, one for the revocation and the other for the provider agreement termination) involving a revoked OTP. The same concern, of course, would apply in the reverse situation, in which a termination of the provider agreement under § 489.53 led to a revocation under § 424.535 because a provider agreement is a requirement for enrollment pursuant to proposed § 424.67(b)(7)(i). We believe that having dual appeals processes for OTPs would impose unnecessary administrative burdens on OTPs and CMS. A single appeals process would, in our view, be more efficient. To this end, we propose in new § 424.67(b)(7)(ii) that an OTP's appeals under 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter. We note that there is precedence for such a consolidated approach. Under §§ 422.222(a)(2)(ii)(B) and 423.120(c)(6)(v)(B)(2) (which apply to Medicare Part C and D, respectively), if a provider's or prescriber's inclusion on the preclusion list (*see https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html* for background information on the preclusion list) is based on a contemporaneous Medicare revocation under § 424.535, the appeals of the preclusion list inclusion and the revocation must be filed jointly and considered jointly under part 498.

We would appreciate comment on our proposed consolidated appeals process, including suggestions of alternative processes and the potential operational components thereof.

(h) OTPs: Other Applicable Requirements

To ensure that the OTP meets all other applicable requirements for enrollment, we are proposing at § 424.67(b)(8)) that the OTP must comply with all other applicable requirements for enrollment specified in § 424.67 and in part 424, subpart P.

(i) OTPs: Denial of Enrollment and Appeals Thereof

We are proposing to state in new § 424.67(c)(1)(i) and (ii) that CMS may deny an OTP's enrollment application on either of the following grounds:

- The provider does not have in effect a current, valid certification by SAMHSA as required under § 424.67(b)(4) or fails to meet any other applicable requirement in § 424.67.
- Any of the reasons for denial of a prospective provider's or supplier's enrollment application in § 424.530 applies.

In new § 424.67(c)(2), we are proposing that an OTP may appeal the denial of its enrollment application under part 498.

We believe that § 424.67(c)(1)(i) is necessary so as to comply with the previously mentioned statutory and regulatory requirements that an OTP be SAMHSA-certified. Concerning paragraphs (c)(1)(ii) and (2), we note that because an OTP is a Medicare provider, it must be treated in the same manner as any other provider or supplier for purposes of enrollment and appeal rights; that is, subpart P and the appeals provisions in part 498 apply to OTPs to the same extent they do to all other providers and suppliers. We accordingly believe it is appropriate to include paragraphs (c)(1)(ii) and (2) in this proposed rule.

(j) OTPs: Continued Compliance, Standards, and Reasons for Revocation

For reasons identical to those behind our proposed addition of paragraph (c), we propose several provisions in new § 424.67(d).

In paragraph (d)(1), we are proposing to state that, upon and after enrollment, an OTP:

- Must remain validly certified by SAMHSA as required under § 8.11.
- Remains subject to, and must remain in full compliance with, the provisions of part 424, subpart P and

those in § 424.67. This includes, but is not limited to, the provisions of § 424.67(b)(6), the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

In paragraph (d)(2), we are proposing that CMS may revoke an OTP's enrollment if:

- The provider does not have a current, valid certification by SAMHSA or fails to meet any other applicable requirement or standard in § 424.67, including, but not limited to, the OTP standards in §§ 424.67(b)(6) and (d)(1).
- Any of the revocation reasons in § 424.535 applies.

Finally, in new paragraph (d)(3), we are proposing that an OTP may appeal the revocation of its enrollment under part 498.

(k) OTPs: Prescribing Individuals

We believe it is important for us to be able to monitor the prescribing and dispensing practices occurring at an OTP. We have an obligation to ensure that beneficiary safety is maintained and the Trust Funds are protected. Accordingly, we propose under new § 424.67(e)(1) (and with respect to payment to OTP providers for furnished drugs) that the prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 (the ordering/referring/other field) of the Form CMS–1500 (Health Insurance Claim Form; 0938–1197) (or the digital equivalent thereof)). We note that our use of the term ''medication ordering'' is merely intended to reiterate that our proposed provision applies to any physician or other eligible professional who prescribes or orders drugs in the OTP arena.

Section 424.67(e)(1), in our view, would help us: (1) Ensure that the physician or other eligible professional in question is qualified to prescribe drugs on behalf of the OTP; and (2) monitor the prescribing individual in relation to each claim. This requirement would have to be met in order for an OTP claim for a prescribed drug to be paid. So as to avoid the impression, however, that this is the only requirement necessary for claim payment, we propose to further clarify in new paragraph (e)(2) that all other applicable requirements in § 424.67, part 424, and part 8 must also be met.

(l) OTPs: Relationship to 42 CFR Part 8

To help ensure that OTPs understand their continuing need to comply with the provisions in part 8 (several of which are referenced above) and to clarify that the provisions in § 424.67 are generally restricted to the enrollment process, we propose to state in new § 424.67(f) that § 424.67 shall not be construed as: (1) Supplanting any of the provisions in part 8; or (2) eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8.

(m) Effective and Retrospective Date of OTP Billing Privileges

Section 424.520 of Title 42 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location In a similar vein, § 424.521(a) states that physicians, non-physician practitioners, physician and non-physician practitioner organizations, and ambulance suppliers may retrospectively bill for services when the supplier has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to:

- 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days prior to their effective date if a Presidentially-declared disaster under the *Robert T. Stafford Disaster Relief and Emergency Assistance Act,* 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

To clarify the effective date of billing privileges for OTPs and to account for circumstances that could prevent an OTP's enrollment prior to the furnishing of Medicare services, we propose to include newly enrolling OTPs within the scope of both § 424.520(d) and § 424.521(a). We believe that the effective and retrospective billing dates addressed therein achieves a proper balance between the need for the prompt provision of OTP services and the importance of ensuring that each prospective OTP enrollee is carefully and closely screened for compliance with all applicable requirements.

2. Revision(s) and Addition(s) to Denial and Revocation Reasons in §§ 424.530 and 424.535

a. Improper Prescribing

Under § 424.535(a)(14), CMS may revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that:

- Is abusive, and/or represents a threat to the health and safety of Medicare beneficiaries; or
- Fails to meet Medicare requirements.

This revocation reason was finalized in the ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule that was published in the May 23, 2014 **Federal Register** (79 FR 29844). It was designed to address situations, which we discussed in that final rule, where prescribers of Part D drugs engaged in prescribing activities that were or could be harmful to Medicare beneficiaries and the Trust Funds or were otherwise inconsistent with Medicare policies. Since the provision's inception, we have revoked the enrollments of practitioners who have engaged in a variety of improper prescribing practices. We believe these administrative actions have helped to shield beneficiaries and the program at large from improper prescribing practices.

The dispensing of drugs in the treatment of opioid use disorder is, as indicated previously, an important component of an OTP's function. Akin to our rationale for the establishment of § 424.535(a)(14) in 2014, we are concerned about potential instances where OTP physicians and other eligible professionals prescribe drugs in an improper fashion. This is an especially important consideration given the nationwide opioid epidemic and the need to reduce opioid abuse. Given this, we believe that § 424.535(a)(14) should no longer be restricted to Part D drugs but must extend to all Medicare drugs, including Part B drugs. Improper prescribing in the Part B context is no less troubling or potentially dangerous than prescribing in the Part D context. Thus, only through such an expansion can we, on a much broader and necessary scale, further deter parties from improper Medicare prescribing practices.

In the introductory text of § 424.535(a)(14), we currently state that CMS determines that the physician or other eligible professional has a pattern or practice of prescribing Part D drugs. Consistent with the above discussion,

we are proposing to revise this paragraph to include Part B drugs so we would specify the prescribing of ''Part B or D drugs.'' We note that this proposal would affect prescriptions of any Part B or D drugs, not merely those prescriptions given to beneficiaries using OTPs.

b. Patient Harm

As referenced previously, and due to the importance of ensuring patient safety in all provider and supplier settings (not merely those involving OTPs), we are also proposing to add § 424.535(a)(22) as a new revocation reason; this would be coupled with a concomitant new denial reason in § 424.530(a)(15). These two paragraphs would permit us to revoke or deny, as applicable, a physician's or other eligible professional's (as that term is defined in 1848(k)(3)(B) of the Act) enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm. In determining whether a revocation or denial on this ground is appropriate, CMS would consider the following factors:

- The nature of the patient harm.
- The nature of the physician's or other eligible professional's conduct.
- The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or other eligible professional by a state oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

++ License restriction(s) pertaining to certain procedures or practices,

++ Required compliance appearances before state oversight board members,

++ Required participation in rehabilitation or mental/behavioral health programs,

++ Required abstinence from drugs or alcohol and random drug testing,

++ License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

++ Administrative/monetary penalties; or

++ Formal reprimand(s).

- If applicable, the nature of the IRO determination(s).
- The number of patients impacted by the physician's or other eligible professional's conduct and the degree of harm thereto or impact upon.
- Any other information that CMS deems relevant to its determination.

We currently lack the legal basis to take administrative action against a physician or other eligible professional for a matter related to patient harm based solely on an IRO determination or an administrative action (excluding a state medical license suspension or revocation) imposed by a state oversight board, a federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. We believe, however, that our general rulemaking authority under sections 1102, 1866(j)(1)(A), and 1871 of the Act gives us the ability to establish such legal grounds. As alluded to in this proposed rule and in previous rulemaking efforts, we have long been concerned about instances of physician or other eligible professional misconduct, and we believe our authority to take action to stem such behavior should be expanded to include the scenarios identified in proposed § 424.530(a)(15) and § 424.535(a)(22). Indeed, state oversight boards, such as medical boards and other administrative bodies, have found certain physicians and other eligible professionals to have engaged in professional misconduct and/or negligent or abusive behavior involving patient harm. IRO determinations, too, have offered valuable, independent analyses and findings of provider misconduct that we should have the opportunity to use to promote the best interests of Medicare beneficiaries. We believe that our proposed revocation and denial authorities would improve overall patient care by preventing certain problematic physicians and other eligible professionals from treating Medicare patients.

We recognize that situations could arise where a state oversight board has chosen to impose a relatively minor sanction on physician or other eligible professional for conduct that we deem more serious. We note, however, that we, rather than state boards, is ultimately responsible for the administration of the Medicare program and the protection of its beneficiaries. State oversight of licensed physicians or practitioners is, in short, a function entirely different from federal oversight of Medicare. We accordingly believe that we should have the discretion to review such cases to determine whether, in the agency's view, the physician's or other eligible professional's conduct warrants revocation or denial. Yet it should in no way be assumed, on the other hand, that a very modest sanction would automatically result in revocation or denial action. We emphasize that we would only take such a measure after the most careful consideration of all of the factors outlined above.

A number of these factors, we add, are not altogether dissimilar from those which we presently use for determining whether a revocation under § 424.535(a)(14) is appropriate (for example, general frequency and degree of the behavior in question, number of prior sanctions). We have found them to be useful in our § 424.535(a)(14) determinations and, for this reason, believe they will prove likewise with respect to § 424.530(a)(15) and § 424.535(a)(22). Certain of our other proposed criteria are designed to pertain to the unique facts addressed in these two provisions (for example, the extent of patient harm) and, in our view, would help ensure a thorough review of the case at hand.

Sections 424.530(a)(15) and 424.535(a)(22) would apply to physicians and other eligible professionals in OTP and non-OTP settings. Revocation or denial action could be taken against physicians and other eligible professionals in solo practice or who are part of a group or any other provider or supplier type.

To clarify the scope of the term ''state oversight board'' in the context of §§ 424.530(a)(15) and 424.535(a)(22), we propose to define this term in § 424.502. Specifically, we would state that, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, ''state oversight board'' means ''any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the state.''

We welcome comment not only on our proposed definition of ''state oversight board'' but also on our proposed revocation and denial authorities. We are especially interested in securing public feedback on additional means of preventing fraud, waste, and abuse in OTP setting; for instance, we would appreciate suggestions—based on stakeholder experience in the OUD and OTP arenas—from which we could develop further regulatory authority to take action against problematic OTPs.

I. Deferring to State Scope of Practice Requirements

When the Medicare program was signed into law in 1965, most skilled medical professional services in the United States were provided by physicians, with the assistance of nurses. Over the decades, the medical professional field has diversified and allowed for a wider range of certifications and specialties, including the establishment of mid-level practitioners such as nurse practitioners (NPs) and physician assistants (PAs). These practitioners are also known as advanced practice providers (APPs) or non-physician practitioners (NPPs). Medicare policies and regulations have been updated over recent years to make changes to allow NPPs to provide services in Medicare-certified facilities within the extent of their scope of practice as defined by state law. In recognition of the qualifications of these practitioners, we seek to continue this effort.

1. Ambulatory Surgical Centers

a. Background

Ambulatory surgical centers (ASCs), as defined at 42 CFR 416.2, are distinct entities that operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization, in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed at ASCs are scheduled, primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. Currently, there are approximately 5,767 Medicare certified ASCs in the United States.

Section 1832(a)(2)(F)(i) of the Act specifies that ASCs must meet health, safety, and other requirements specified by the Secretary in order to participate in Medicare. The Secretary is responsible for ensuring that the ASC Conditions for Coverage (CfCs) protect the health and safety of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients. The ASC regulations were established in the ''Medicare Program; Ambulatory Surgical Services'' final rule published in the August 5, 1982 **Federal Register** (47 FR 34082), and have since been amended several times.

The regulations for Medicare and Medicaid participating ASCs are set forth at 42 CFR part 416. Section 416.42, ''Condition for coverage—Surgical services'', states that surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

Currently, the ASC CfCs have two conditions that include patient assessment requirements for patients having surgery in an ASC, anesthetic risk and pre-surgery evaluation, and pre-discharge evaluation. In the November 18, 2008 final rule, ''Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates final rule (73 FR 68502), which revised some existing standards and created some new requirements. One of the new conditions added in 2008 was § 416.52, ''Conditions for coverage—Patient admission, assessment and discharge''. This condition sets standards pertaining to patient pre-surgical assessment, post-surgical assessment, and discharge requirements that must be met before patients leave the ASC. Specifically, the discharge requirements at § 416.52(b)(1) require that a post-surgical assessment be completed by a physician, or other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable state health and safety laws, standards of practice, and ASC policy. The other discharge condition, at § 416.42(a)(2), also finalized in the November 18, 2008 final rule, allows anesthetists, in addition to physicians, to evaluate each patient for proper anesthesia recovery. The requirement at § 416.42(a)(1) requires a physician to examine the patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed.

Through various inquiries from ASCs and communication with CMS by industry associations, we have received many requests to align the anesthetic risk and pre-surgery evaluation standard at § 416.42(a)(1) with the pre-discharge standard at § 416.42(a)(2) by allowing an anesthetist, in addition to a physician, to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure. For those ASCs that utilize non-physician anesthetists, also known as certified registered nurse anesthetists (CRNAs), this revision would allow them to perform the anesthetic risk and evaluation on the patient they are anesthetizing for the procedure to be performed by the physician. CRNAs are advanced practice registered nurses who administer more than 43 million anesthetics to patients each year in the United States. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the PFS amount for services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in most rural hospitals. A study published by Nursing Economic$ in May/June 2010, found that CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measureable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.[101] We believe this alignment provides for continuity of care for the patient and allows the patient's anesthesia professional to have familiarity with the patient's health characteristics and medical history.

b. Proposed Provisions

We are proposing to revise § 416.42(a), Surgical services, to allow either a physician or an anesthetist, as defined at § 410.69(b), to examine the patient immediately before surgery to evaluate the risk of anesthesia and the risk of the procedure to be performed. By amending the CfCs to allow an anesthetist or a physician to examine and evaluate the patient before surgery for anesthesia risk and the planned procedure risk, we would be making ASC patient evaluations more consistent by allowing the option for the same clinician to complete both pre- and post-procedure anesthesia evaluations.

This proposed change is a continuation of our efforts to reduce regulatory burden. This change would increase supplier flexibility and reduce burden, while allowing qualified clinicians to focus on providing high-quality healthcare to their patients. We are also requesting comments and suggestions for other ASC requirements that could be revised to allow greater flexibility in the use of NPPs, and reduce burden while maintaining high quality health care.

2. Hospice

a. Background

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual, and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define ''palliative care'' as patient and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual,

[101] Paul F. Hogan et al., ''Cost Effectiveness Analysis of Anesthesia Providers.'' Nursing Economic$. 2010; 28:159–169.

emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. The hospice interdisciplinary group works with the patient, family, caregivers, and the patient's attending physician (if any) to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families and caregivers about changes in their condition. The care plan will shift over time to meet the changing needs of the patient, family, and caregiver(s) as the patient approaches the end of life.

The regulations for Medicare and Medicaid participating hospices are set forth at 42 CFR part 418. Section 418.3 defines the term ''attending physician'' as being a doctor of medicine or osteopathy, an NP, or a PA in accordance with the statutory definition of an attending physician at section 1861(dd)(3)(B) of the Act. Section 51006 of the Bipartisan Budget Act of 2018 revised the statute to add PAs to the statutory definition of the hospice attending physician for services furnished on or after January 1, 2019. As a result, PAs were added to the definition of a hospice attending physician as part of the ''Medicare Program; FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements'' final rule which was published in the August 6, 2018 **Federal Register** (83 FR 38622, 38634) (hereinafter referred to as the ''FY 2019 Hospice final rule'').

The role of the patient's attending physician, if the patient has one, is to provide a longitudinal perspective on the patient's course of illness, care preferences, psychosocial dynamics, and generally assist in assuring continuity of care as the patient moves from the traditional curative care model to hospice's palliative care model. The attending physician is not meant to be a person offered by, selected by, or appointed by the hospice when the patient elects to receive hospice care. Section 418.64(a) of the hospice regulations requires the hospice to provide physician services to meet the patient's hospice-related needs and all other care needs to the extent that those needs are not met by the patient's attending physician. Thus, if a patient does not have an attending physician relationship prior to electing hospice care, or if the patient's attending physician chooses to not participate in the patient's care after the patient elects to receive hospice care, then the hospice is already well-suited to provide physician care to meet all of the patient's needs as part of the Medicare hospice benefit. If the patient has an attending physician relationship prior to electing hospice care and that attending physician chooses to continue to be involved in the patient's care during the period of time when hospice care is provided, the role of the attending physician is to consult with the hospice interdisciplinary group (also known as the interdisciplinary team) as described in § 418.56, and to furnish care for conditions determined by the hospice interdisciplinary group to be unrelated to the terminal prognosis. The hospice interdisciplinary group must include the following members of the hospice's staff: A physician; a nurse; a social worker; and a counselor. The interdisciplinary group may also include other members based on the specific services that the patient receives, such as hospice aides and speech language pathologists. The hospice interdisciplinary group, as a whole, in consultation with the patient's attending physician (if any), the patient, and the patient's family and caregivers, are responsible for determining the course of the patient's hospice care and establishing the individualized plan of care for the patient that is used to guide the delivery of holistic hospice services and interventions, both medical and non-medical in nature.

b. Proposed Provisions

In the role of a consultant to the hospice interdisciplinary group, the hospice patient's chosen attending physician may, at times, write orders for services and medications as they relate to treating conditions determined to be unrelated to the patient's terminal prognosis. The law allows for circumstances in which services needed by a hospice beneficiary would be completely unrelated to the terminal prognosis, but we believe that this situation would be the rare exception rather than the norm. Section 418.56(e) requires hospices to coordinate care with other providers who are also furnishing care to the hospice patient, including the patient's attending physician who is providing care for conditions determined by the hospice interdisciplinary group to be unrelated to the patient's terminal prognosis. As part of this coordination of care, it is possible that hospices may receive orders from the attending physician for drugs that are unrelated to the patient's terminal prognosis.

The FY 2019 Hospice final rule amended the regulatory definition of attending physician, as required by the statute, to include physician assistant. Following publication of the FY 2019 Hospice final rule, stakeholders raised concerns regarding the requirements of § 418.106(b). As currently written, hospices may not accept orders for drugs from attending physicians who are PAs because § 418.106(b) specifies that hospices may accept drug orders from physicians and NPs only. This regulatory requirement may impede proper care coordination between hospices and attending physicians who are PAs, and we believe that it should be revised.

Therefore, we propose to revise § 418.106(b)(1) to permit a hospice to accept drug orders from a physician, NP, or PA. We propose that the PA must be an individual acting within his or her state scope of practice requirements and hospice policy. We also propose that the PA must be the patient's attending physician, and that he or she may not have an employment or contractual arrangement with the hospice. The role of physicians and NPs as hospice employees and contractors is clearly defined in the hospice CoPs; however, the CoPs do not address the role of PAs. Therefore, we believe that it is necessary to limit the hospice CoPs to accepting only those orders from PAs that are generated outside of the hospice's operations.

The role of a PA is not defined in the hospice CoPs because the statute does not include PA services as being part of the Medicare hospice benefit. As such, there are no provisions in the hospice CoPs to address specific PA issues such as personnel requirements, descriptions of whether such services would be considered core or non-core, or provisions to address issues of co-signatures. To more fully understand the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs, we request public comment on the following questions:

- What is the role of a NPP in delivering safe and effective hospice care to patients? What duties should they perform? What is their role within the hospice interdisciplinary group and how is it distinct from the role of the physician, nurse, social work, and counseling members of the group?

- Nursing services are a required core service within the Hospice benefit, as provided in section 1861(dd)(B)(i) of the Act, which resulted in the defined role for NPs in the Hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?
- In light of diverse existing state supervision requirements, how should NPP services be supervised? Should this responsibility be part of the role of the hospice medical director or other physicians employed by or under contract with the hospice? What constitutes adequate supervision, particularly when the NPP and supervising physician are located in different offices, such as hospice multiple locations?
- What requirements and time frames currently exist at the state level for physician co-signatures of NPP orders? Are these existing requirements appropriate for the hospice clinical record? If not, what requirements are appropriate for the hospice clinical record?
- What are the essential personnel requirements for PAs and other NPPs?

J. Advisory Opinions on the Application of the Physician Self-Referral Law

1. Statutory and Regulatory Background

Section 4314 of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted August 5, 1997), added section 1877(g)(6) to the Act. Section 1877(g)(6) of the Act requires the Secretary to issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. On January 9, 1998, the Secretary issued a final rule with comment period in the **Federal Register** to implement and interpret section 1877(g)(6) of the Act (the 1998 CMS advisory opinions rule). (See Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions (63 FR 1646).) The regulations are codified in §§ 411.370 through 411.389 (the physician self-referral advisory opinion regulations).

Section 1877(g)(6)(A) of the Act states that each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion. Section 1877(g)(6)(B) of the Act requires the Secretary, in issuing advisory opinions regarding the physician self-referral law, to apply the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, to the extent practicable. This paragraph also requires the Secretary to take into account the regulations promulgated under paragraph (b)(5) of section 1128D of the Act.

Section 1128D of the Act was added to the statute by section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, effective August 21, 1996). Among other things, section 1128D of the Act requires the Secretary, in consultation with the Attorney General, to issue written advisory opinions as to specified matters related to the anti-kickback statute in section 1128B(b) of the Act, the safe harbor provisions in § 1001.952, and other provisions of the Act under the authority of the Office of Inspector General (OIG). To implement and interpret section 1128D of the Act, the Office of Inspector General (OIG) issued an interim final rule with comment period in the February 19, 1997 **Federal Register** entitled Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG (62 FR 7350), revised and clarified its regulations in the July 16, 1998 **Federal Register** (68 FR 38311), and updated its regulations in a final rule published in the July 17, 2008 **Federal Register** that solely revised certain procedural requirements for submitting payments for advisory opinion costs (73 FR 40982) (collectively, the OIG advisory opinion rule). The regulations are codified in part 1008 of this title of the Code of Federal Regulations (the OIG advisory opinion regulations).

Section 1128D(b)(3) of the Act prohibits the Secretary from addressing in an advisory opinion whether: (1) Fair market value shall be or was paid or received for any goods, services, or property; or (2) an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986. In the 1998 CMS advisory opinions rule, we incorporated these provisions into the physician self-referral law regulations (63 FR 1646). Section 1128D(b)(4)(A) of the Act states that an advisory opinion related to OIG authorities is binding as to the Secretary and the party or parties requesting the opinion. This section is redundant of the provision in section 1877(g)(6)(A) of the Act, and therefore, not incorporated into the physician self-referral advisory opinion regulations. Section 1128D(b)(4)(B) of the Act provides that the failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B of the Act. We incorporated section 1128D(b)(4)(B) of the Act in the physician self-referral regulations at § 411.388.

As discussed previously, section 1877(g)(6)(B) of the Act requires the Secretary, to the extent practicable, to take into account the regulations issued under the authority of section 1128D(b)(5) of the Act (that is, the OIG advisory opinion regulations). Section 1128D(b)(5)(A) requires that the OIG advisory opinion regulations must provide for: (1) The procedure to be followed by a party applying for an advisory opinion; (2) the procedure to be followed by the Secretary in responding to a request for an advisory opinion; (3) the interval in which the Secretary will respond; (4) the reasonable fee to be charged to the party requesting an advisory opinion; and (5) the manner in which advisory opinions will be made available to the public. We interpret Congress' directive to take into account OIG regulations to mean that we should use the OIG regulations as our model, but that we are not bound to follow them (63 FR 1647). Nonetheless, in the 1998 CMS advisory opinions rule, we largely adopted OIG's approach to issuing advisory opinions, stating that we intend for physician self-referral law advisory opinions to provide the public with meaningful advice regarding whether, based on specific facts, a physician's referral for a designated health service (other than a clinical laboratory service) is prohibited under section 1877 of the Act (63 FR 1648).

2. Proposed Revisions to the CMS Advisory Opinion Process and Regulations

In the June 25, 2018 **Federal Register**, we published a Request for Information Regarding the Physician Self-Referral Law (83 FR 29524) (June 2018 CMS RFI) that sought recommendations from the public on how to address any undue impact and burden of the physician self-referral statute and regulations. Although we did not specifically request comments on the CMS advisory opinion regulations, we received a number of comments urging that CMS reconsider its approach to advisory opinions and transform the process such that the regulated industry may obtain expeditious guidance on whether a physician's referrals to an entity with which he or she has a financial relationship would be prohibited under section 1877 of the Act. These commenters stated their belief that the current advisory opinion process could be improved. Some commenters stated also that the process is too restrictive, noting that CMS has placed what the commenters see as unreasonable limits on the types of questions that qualify for

an advisory opinion (for example, CMS will not issue an advisory opinion where the arrangement at issue is hypothetical and does not issue advisory opinions on general questions of interpretation) and CMS advisory opinions apply only to the specific circumstances of the requestor. These commenters asserted that the OIG's advisory opinion process, upon which the CMS advisory opinion process is modeled, is inappropriate for a payment statute. These commenters noted that OIG opines on matters related to a felony criminal statute, whereas the physician self-referral law, by contrast, is a payment rule. The commenters highlighted the complexity of the physician self-referral regulations, the strict liability nature of the physician self-referral law, and the need for certainty before arrangements are initiated and claims submitted as reasons why an advisory opinion process related to a felony criminal statute is inappropriate for the physician self-referral law. Other commenters asserted that the process is arduous and inefficient. These commenters noted that the advisory opinion process can extend beyond the 90-day timeframe provided for at § 411.380 and asserted that it lags behind the OIG process in terms of efficiency.

In designing its advisory opinion process, OIG carefully balanced stakeholders' desire for an accessible process and meaningful and informed opinions with its need to closely scrutinize arrangements to insure that requesting parties are not inappropriately granted protection from sanctions. (63 FR 38312 through 38313). We appreciate that there are important differences between the physician self-referral law, a strict liability statute designed to prevent payment for services where referrals are affected by inherent financial conflicts of interest, and the anti-kickback statute, which is a criminal law designed to prosecute intentional acts of fraud and abuse.

More than 20 years have passed since the CMS advisory opinion regulations were issued. In those 20 years, we have issued 30 advisory opinions,[102] 15 of which addressed the 18-month moratorium on physician self-referrals to specialty hospitals in which they have an ownership or investment interest. In light of the comments received on the RFI, we have undertaken a fresh review of the CMS advisory opinion process. We agree that it is important to have an accessible process that produces meaningful opinions on the applicability of section 1877 of the Act, especially in light of the perceived complexity of the physician self-referral regulations, including the requirements of the various exceptions and the key terminology applicable to many of the exceptions, and we recognize that our current advisory opinion process has not been utilized by stakeholders or resulted in a significant number of issued opinions to date. Accordingly, we have reviewed our advisory opinion regulations in an effort to identify limitations and restrictions that may be unnecessarily serving as an obstacle to a more robust advisory opinion process.

Failure to satisfy the requirements of an exception to the physician self-referral law carries significant consequences, regardless of a party's intent.[103] The safe harbors under the anti-kickback statute are voluntary, and the failure of an arrangement to fit squarely within a safe harbor does not mean that the arrangement violates the anti-kickback statute. By contrast, the physician self-referral law prohibits a physician's referral if there is a financial relationship that does not satisfy the requirements of one of the enumerated exceptions. In other words, the physician self-referral law is a strict liability law, and parties that act in good faith may nonetheless face significant financial exposure if they misunderstand or misapply the law's exceptions.

Regulated parties' desire for certainty must be balanced with CMS' interest in maintaining the integrity of the advisory opinion process, and ensuring that it is not used to inappropriately shield improper financial arrangements. But we believe that the risk of such misuse is acceptably low with respect to the section 1877 of the Act advisory opinion process because the advisory opinion authority at section 1877(g) of the Act is narrowly tailored. CMS can only issue favorable advisory opinions for arrangements that do not violate section 1877 of the Act—for example, because there is no referral for designated health services, there is no financial relationship, or the arrangement meets an exception. In contrast, OIG has issued favorable advisory opinions for arrangements that do not fit within a safe harbor where it has concluded, based on a totality of the facts and circumstances, that the arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute. CMS cannot similarly extend protection beyond the exceptions, so there is a built-in safeguard against protecting an arrangement that the law would not otherwise protect. Furthermore, a favorable advisory opinion from CMS does not immunize parties from liability under the anti-kickback statute.

a. Matters Subject to Advisory Opinions (§ 411.370)

Section 1877(g)(6) of the Act requires the Secretary to issue advisory opinions concerning ''whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section.'' In accordance with section 1877(g)(6)(B) of the Act, CMS adopted in regulation the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, which prohibit the OIG from opining on whether an arrangement is fair market value and whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code. In addition to these statutory restrictions on matters that are not subject to advisory opinions, our current regulation at § 411.370(b)(1) states that CMS does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties. When explaining this regulation, we stated that we interpret section 1877(g)(6) of the Act to allow for opinions on specific referrals involving physicians in specific situations (63 FR 1649). We also noted our reasons for avoiding opinions on generalized arrangements, stating that it would not be possible for an advisory opinion to reliably identify all the possible hypothetical factors that might lead to different results (*Id.*).

Under our current regulations, CMS accepts requests for advisory opinions that involve existing arrangements, as well as requests that involve arrangements into which the requestor plans to enter. Some commenters on the June 2018 CMS RFI suggested that CMS expand the scope of the requests that it will consider for an advisory opinion to include requests that involve hypothetical fact patterns and general questions of interpretation. It is our position that some requests are not appropriate for an advisory opinion.

[102] These advisory opinions are available on CMS' website, at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory opinions.html.* This number does not include advisory opinion requests that were withdrawn.

[103] The CMS Voluntary Self-Referral Disclosure Protocol (SRDP) allows providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute. Under the SRDP, CMS may reduce the amount due and owing for violations of section 1877 of the Act. Information about the SRDP can be found at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf.*

Further, although we are proposing a number of changes to improve the advisory opinion process for stakeholders, we believe that expanding the process to include questions regarding hypothetical fact patterns or general interpretation could overwhelm the agency. Thus, we are not proposing an expansion of the scope of requests at this time; however, we are soliciting comments on whether we should do so in the future. We are proposing minor clarifications to § 411.370(b) regarding matters that qualify for advisory opinions and the parties that may request them. Specifically, we are proposing to clarify that the request for an advisory opinion must ''relate to'' (rather than ''involve'') an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. Requestors continue to be obligated to disclose all facts relevant to the arrangement for which an advisory opinion is sought. We are also proposing revisions to the regulation text for grammatical purposes.

We note that CMS currently responds to questions pertaining to the physician self-referral law through the CMS Physician Self-Referral Call Center. Although we are unable to provide formal guidance or an opinion regarding whether a specific referral is permissible or whether a financial relationship satisfies the requirements of an exception, we are able to assist parties with identifying relevant guidance. The CMS Physician Self-Referral Call Center is free to the public, and inquiries may be sent to *1877CallCenter@cms.hhs.gov*. For additional information, *see https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Call-Center.html*. CMS also responds to frequently asked questions (FAQs) regarding the physician self-referral law from time to time. FAQs issued to date may be found on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html*.

Current § 411.370(e) states that CMS does not accept an advisory opinion request or issue an advisory opinion if: (1) The request is not related to a named individual or entity; (2) CMS is aware that the same or substantially the same course of action is under investigation or is or has been the subject of a proceeding involving HHS or another governmental agency; or (3) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry. We are proposing changes to this regulation. First, we are proposing to add to the reasons that CMS will not accept an advisory opinion request or issue an advisory opinion. Specifically, we are proposing that CMS will reject an advisory opinion request or not issue an advisory opinion with respect to a request that does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information. We believe that this is important to the agency's ability to focus its resources on complete requests.

Second, we are proposing to amend current § 411.370(e)(2), which states that CMS will not issue an advisory opinion if it is aware that the same, or substantially the same, course of action is under investigation or is or has been the subject of a proceeding involving HHS or other government entities. Although CMS consults with other HHS components and governmental agencies, including OIG and DOJ, on pending advisory opinion requests, we believe the current regulation is too restrictive, and unnecessarily limits CMS' flexibility to issue timely guidance to requestors engaged in or considering legitimate business arrangements. Therefore, we are proposing to ease the restriction at § 411.370(e)(2) that prohibits the acceptance of an advisory opinion request or issuance of an advisory opinion if CMS is aware of pending or past investigations or proceedings involving a course of action that is ''substantially the same'' as the arrangement or proposed arrangement between or among the parties requesting an advisory opinion, and instead allow CMS more discretion to determine, in consultation with OIG and DOJ, whether acceptance of the advisory opinion request or issuance of the advisory opinion is appropriate. Specifically, we propose at § 411.370(e)(2) that CMS may elect not to accept an advisory opinion request or issue an advisory opinion if, after consultation with OIG and DOJ, it determines that the course of action described in the request is substantially similar to conduct that is under investigation or is the subject of a proceeding involving HHS or other law enforcement agencies, and issuing an advisory opinion could interfere with the investigation or proceeding. We propose to retain at renumbered § 411.370(e)(1)(iii) the restriction on accepting requests if CMS is aware that the specific course of action (involving the same specific parties) is under investigation or is, or has been the subject of a proceeding involving the Department or another governmental agency. We also propose to clarify that CMS would consult with OIG and DOJ regarding investigations or proceedings involving the same course of conduct described in an advisory opinion request. We seek comments on this approach.

Although we are not proposing changes to § 411.370(f) which describes the effects of an advisory opinion on other government authority, we note that a determination regarding whether a referral is prohibited by section 1877 of the Act is a determination that rests solely and exclusively with the Secretary (and, in this case, the Administrator, to whom the Secretary has delegated this authority). Under section 1877(g)(6) of the Act, an advisory opinion is binding on the Secretary, and if the Secretary determines that a particular fact pattern does not trigger liability under section 1877 of the Act, that determination is binding on the Secretary, as well as any component of HHS that exercised the authority delegated by the Secretary. Such a determination would preclude the imposition of sanctions under section 1877(g) of the Act.[104] A favorable advisory opinion would not, however, insulate parties from liability under the anti-kickback statute or any other laws or regulations outside of section 1877 of the Act. It would also not preclude OIG from exercising its authority under the Inspector General Act of 1978 (Pub. L. 95–452, as amended by Pub. L. 115–254, enacted October 05, 2018). In a physician self-referral law advisory opinion, CMS may opine on whether an arrangement is ''commercially reasonable'' as defined by the physician-self-referral law regulations. Such a determination by CMS may not apply in the context of the anti-kickback statute and should not be interpreted as such. A CMS determination that an arrangement is or is not a ''financial relationship,'' as defined at section 1877(a)(2) of the Act and § 411.354(a), or that an arrangement satisfies a specific requirement of an exception to the physician self-referral law (for example, whether a compensation arrangement is ''commercially reasonable''), would be a separate and distinct inquiry from any determination by law enforcement that the arrangement does or does not violate the anti-kickback statute.

b. Timeline for Issuing an Advisory Opinion (§ 411.380)

Section 1877(g)(6) of the Act does not impose any deadlines by which the

[104] The Secretary has delegated the civil monetary penalty authority under section 1877 of the Act to the OIG.

agency must respond to an advisory opinion request, but section 1128D(b)(5)(B)(i) of the Act provides that the Secretary shall be required to issue an advisory opinion no later than 60 days after the request is received. In the 1998 CMS advisory opinions rule, we adopted a 90-day timeframe for most requests. In addition, for requests that we determine, in our discretion, involve complex legal issues or highly complicated fact patterns, we reserved the right to issue an advisory opinion within a reasonable timeframe. We created this timeframe based upon our estimates on the volume and complexity of expected requests, and based upon our then-current staffing situation.

We are proposing to modify this time period and establish a 60-day timeframe for issuing advisory opinions. The 60-day period would begin on the date that CMS formally accepts a request for an advisory opinion. The 60 days would be tolled during any time periods in which the request is being revised or additional information compiled and presented by the requestor. We are also considering whether CMS should provide requestors with the option to request expedited review. We believe that a more efficient and expeditious process could give stakeholders more certainty and encourage innovative care delivery arrangements. We seek comment on the proposed changes to the timeframe, whether CMS in the final rule should include a provision on expedited review and, if so, the parameters for expedited review.

c. Certification Requirement (§ 411.373)

In the 1998 CMS advisory opinions rule, we adopted a requirement identical to OIG's requirement that a requestor must certify to the truthfulness of its submissions, including its good faith intent to enter into proposed arrangements. CMS finalized regulations that require a requestor to make two certifications as part of its request for an advisory opinion. Under current § 411.373(a), the requestor must certify that, to the best of the requestor's knowledge, all of the information provided as part of the request is true and correct and constitutes a complete description of the facts regarding which an advisory opinion is being sought. If the request relates to a proposed arrangement, current § 411.373(b) states that the request must also include a certification that the requestor intends in good faith to enter into the arrangement described in the request. A requestor may make this certification contingent upon receiving a favorable advisory opinion from CMS or from both CMS and OIG. Under current § 411.372(b)(8), if the requestor is an individual, the individual must sign the certification; if the requestor is a corporation, the certification must be signed by the Chief Executive Officer, or a comparable officer; if the requestor is a partnership, the certification must be signed by a managing partner; and, if the requestor is a limited liability company, the certification must be signed by a managing member. We are proposing to revise § 411.372(b)(8) to clarify that the certification must be signed by an officer that is authorized to act on behalf of the requestor. We are also considering whether it would be appropriate to eliminate the certification requirement in our regulations, given that section 1001 of Title 18 of the United States Code prohibits material false statements in matters within the jurisdiction of a federal agency. We seek comment on whether the existing certification requirement creates undue burden for requestors, and whether the requirement is necessary given Section 1001.

d. Fees for the Cost of Advisory Opinions (§ 411.375)

In the 1998 CMS advisory opinions rule, we established a fee that is charged to requestors to cover the actual costs incurred by CMS in responding to a request for an advisory opinion. Under current § 411.375, there is an initial fee of $250, and parties are responsible for any additional costs incurred that exceed the initial $250 payment. A requestor may designate a triggering dollar amount, and CMS will notify the requestor if CMS estimates that the costs of processing the request have reached or are likely to exceed the designated triggering amount. This fee structure was modeled after OIG regulations that were in effect at that time.

Since CMS issued the 1998 CMS advisory opinions rule, OIG has updated its regulations to eliminate the initial fee, and instead charges requesting parties a consolidated final payment based on costs associated with preparing an opinion (73 FR 15936). We believe it is appropriate to adopt an hourly fee of $220 for preparation of an advisory opinion. We believe this amount reflects the costs incurred by the agency in processing an advisory opinion request. We are also considering adding a provision establishing an expedited pathway for requestors that seek an advisory opinion within 30 days of the request. If we establish such a pathway, we would consider charging $440 an hour to process the request, reflecting the extra resources necessary to produce an advisory opinion within the abbreviated timeframe. We request comments on this approach. To ensure that obtaining an advisory opinion is affordable, and to prevent unfair surprises to requestors at the end of the process, we are considering promulgating a cap on the amount of fees charged for an advisory opinion. We solicit comments on the amount of the cap. We also request comments on whether CMS should eliminate the initial $250 fee.

e. Reliance on an Advisory Opinion (§ 411.387)

As we consider improvements to the advisory opinion process, we are also considering regulatory changes to clarify current CMS policies and practices, and make our advisory opinions more useful compliance tools for stakeholders. Specifically, we are soliciting comment on proposals, described in more detail below, to remove some of the regulatory provisions limiting the universe of individuals and entities that can rely on an advisory opinion, and to add language expressing what we believe are permissible uses of an advisory opinion.

Section 1877(g)(6)(A) of the Act states that an advisory opinion shall be binding on the Secretary and on the party or parties requesting an opinion. Consistent with the policy adopted by OIG, CMS took the view that an advisory opinion may legally be relied upon only by the requestors. While section 1877 of the Act is silent on how third parties may use an advisory opinion, in regulation, CMS has precluded legal reliance on the opinion by non-requestor third parties. At the time, we stated that advisory opinions are capable of being misused by persons not a party to the transaction in question in order to inappropriately escape liability (63 FR 1648). While such a preclusion may be appropriate for purposes of an OIG advisory opinion on the application of a criminal statute, we believe it may be unduly restrictive in the context of a strict liability payment rule that applies regardless of a party's intent.

In practice, CMS does anticipate that parties to an arrangement that is subject to a favorable advisory opinion will rely on the opinion, even if the parties did not join in the request. If, for instance, CMS determines that an arrangement does not constitute a financial relationship because it satisfies all requirements of an applicable exceptions to the physician self-referral law, that determination would necessarily apply equally to any individuals and entities that are parties to the specific arrangement, for example, the referring physician and the entity to which he or she refers patients

for designated health services. Thus, even if the physician party to the arrangement was not a requestor of the advisory opinion, the physician party is entitled to rely on that advisory opinion. We are proposing changes to § 411.387 to reflect this view. Specifically, we are proposing at § 411.387(a) that an advisory opinion would be binding on the Secretary and that a favorable advisory opinion would preclude the imposition of sanctions under section 1877(g) of the Act with respect to the party or parties requesting the opinion and any individuals or entities that are parties to the specific arrangement with respect to which the advisory opinion is issued.

We are proposing at § 411.387(b) that the Secretary will not pursue sanctions under section 1877(g) of the Act against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the advisory opinion. Even though a favorable advisory opinion with respect to one arrangement would not legally preclude CMS from pursuing violations against parties to a different arrangement, in practice, the Secretary would not consider using enforcement resources for purposes of imposing sanctions under section 1877(g) of the Act to investigate the actions of parties to an arrangement that CMS believes is materially indistinguishable from an arrangement that has received a favorable advisory opinion. As discussed above, such a determination would not preclude a finding by DOJ or OIG that the arrangement violates the anti-kickback statute or any other law. All facts relied on and influencing a legal conclusion in an issued favorable advisory opinion are material; deviation from that set of facts would result in a party not being able to claim the protection proposed in § 411.387(b). If parties to an arrangement are uncertain as to whether CMS would view it as materially indistinguishable from an arrangement that has received a favorable advisory opinion, then those parties can submit an advisory opinion request to query whether a referral is prohibited under section 1877 of the Act because the arrangement is materially indistinguishable from an arrangement that received a favorable advisory opinion. We seek comment on this approach.

Finally, we are also proposing at § 411.387(c) to recognize that individuals and entities may reasonably rely on an advisory opinion as non-binding guidance that illustrates the application of the self-referral law and regulations to specific facts and circumstances. We believe that stakeholders already look to advisory opinions issued by OIG and CMS to inform their decision-making, and these proposed changes would make clear that CMS acknowledges that such reliance is permissible and reasonable. We request comments on all aspects of these proposals.

f. Rescission (§ 411.382)

Under current § 411.382, CMS may rescind or revoke an advisory opinion after it is issued. To date, CMS has not rescinded an advisory opinion. At the time we finalized this regulation, which is modeled on OIG's rescission authority regulation, we sought comment on whether this approach reasonably balanced the government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality (63 FR 1653). We are again requesting comment on this issue. Specifically, we are soliciting comments on whether CMS should retain a more limited right to rescind an advisory opinion; that is, CMS could rescind an advisory opinion only when there is a material regulatory change that impacts the conclusions reached, or when a party has received a negative advisory opinion and wishes to have the agency reconsider the request in light of new facts or law.

g. Other Modifications to Procedural Requirements

We are proposing minor modifications to § 411.372 to improve readability and clarity. We are also proposing to eliminate the reference to the provision of stock certificates as part of the advisory opinion request submission, as these are typically electronic and may not necessarily list the name of the owner. We are requesting comments on these and other updates to the procedure for submitting an advisory opinion request that will improve the efficiency of the review process.

K. CY 2020 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth changes to the Quality Payment Program starting January 1, 2020, except as otherwise noted for specific provisions. The 2020 performance period of the Quality Payment Program should build upon the foundation that has been established in the first 3 years of the program, which provides a trajectory for clinicians moving to performance-based payments, and will gradually prepare clinicians for the 2022 performance period of the program and the 2024 MIPS payment year. Participation in both tracks of the Quality Payment Program—Advanced Alternative Payment Models (APMs) and Merit-based Incentive Payment System (MIPS)—have increased from 2017 to 2018.[105] The number of QPs—Qualifying APM Participations—nearly doubled from 2017 to 2018, from 99,076 to 183,306 clinicians. In MIPS, 98 percent of eligible clinicians participated in 2018, up from 95 percent in 2017. As the Quality Payment Program continues to mature, CMS recognizes additional long-term improvements will need to occur. Beginning with the 2024 MIPS payment year, the cost performance category will be weighted at 30 percent, which has been gradually increased in the last few years, and the performance threshold will be set at the mean or median of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. Beginning in the 2022 performance period, there will no longer be the same flexibility in establishing the weight of the cost performance category or in establishing the performance threshold. Refer readers to sections III.K.3.c.(2)(a) and III.K.3.e.(2) of this proposed rule for more information about the statutory requirements related to these provisions.

b. Summary of Major Proposals

(1) MIPS Value Pathways Request for Information

CMS is committed to the transformation of MIPS, which will allow for: More streamlined and cohesive reporting; enhanced and timely feedback; and the creation of MIPS Value Pathways (MVPs) of integrated measures and activities that are meaningful to all clinicians from specialists to primary care clinicians and patients. The new MVPs would remove barriers to APM participation and promote value by focusing on quality, interoperability, and cost. Additionally, MVPs would create a cohesive and meaningful participation experience for clinicians by moving away from siloed activities and measures and towards an aligned set of measures that are more relevant to a clinician's scope of practice, while further reducing reporting burden and

[105] Quality Payment Program (QPP) Participation in 2018: Results at a Glance *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/586/2018%20QPP%20Participation%20Results%20Infographic.pdf.*

easing the transition to APMs. MVPs are described in greater detail at section III.K.1.b.(2) and the full Request for Information at section III.K.3.a. of this proposed rule.

(2) Major MIPS Proposals

The major MIPS proposals in this year's proposed rule include a focus on a strategic vision to further transform MIPS by empowering patients and simplifying MIPS to improve value and reduce burden. We envision a future state of the program where patients have the information needed to make informed decisions about their healthcare, clinicians improve health outcomes and quality of care for their patients in alignment with the Meaningful Measures initiative,[106] and the data collection burden is limited in alignment with the Patients over Paperwork initiative.[107] Hence, we are proposing to apply a new MVPs framework to future proposals beginning with the 2021 MIPS Performance Year. MVPs would utilize sets of measures and activities that incorporate a foundation of promoting interoperability and administrative claims-based population health measures and layered with specialty/condition specific clinical quality measures to create both more uniformity and simplicity in measure reporting. The MVP framework will also connect quality, cost, and improvement activities performance categories to drive toward value; integrate the voice of patients; and reduce clinician barriers to movement into Advanced APMs. Further, the MVP framework would reduce the number of performance measures and activities clinicians may select. Ultimately, we believe this would decrease clinician burden and improve performance data quality, while still accounting for different types of specialties and practices. In addition to comments requested on the framework, we are seeking feedback on several implementation elements within section III.K.3.a. of this proposed rule. Within this section, we describe our vision that includes the following:

- Furthering the application of the Meaningful Measures framework.
- Implementing a measure set using additional administrative claims-based quality measures.
- Developing MVPs, using an approach which connects measures and activities from the quality, cost, and improvement activities performance categories; requiring completion of the Promoting Interoperability performance category to maintain alignment with hospitals; and focusing on a specialty or condition to standardize and provide more cohesive reporting and participation.
- Providing timely quality and cost performance data feedback using administrative claims, registry, and electronically submitted data to enhance a clinician self-tracking to facilitate care improvements.
- Enhancing information available to patients to inform decision making, including increasing the patient reported measures in MVPs.

This vision will ultimately help us to better measure and incentivize value, ensure participation is more meaningful to clinicians and their patients, provide information to patients to assist with clinician selection, reduce clinician reporting burden, respond to program concerns, and increase alignment with APMs, and increase alignment with APMs. The RFI solicits comment on the types of information that would be useful to patients (Medicare beneficiaries) and individual clinicians reporting data for purposes of sharing on CMS public websites. We have assessed new opportunities, such as, implementation of a foundational claims-based population health core measure set using administrative claims-based quality measures that can be broadly applied to communities or populations, development of MVP measure tracks to provide uniformity in measure reporting and to unify performance categories, and enhancement of the patient voice, to increase simplicity, reduce burden, and increase the value of MIPS performance data. We strongly encourage feedback on how we can best realize our path to value vision of MIPS Value Pathways.

In addition to this framework, we are making two significant proposals for the 2020 MIPS performance period:

- As discussed in section III.K.3.g.(2) of this proposed rule, we are proposing to strengthen the Qualified Clinical Data Registry (QCDR) measure standards for MIPS to require measure testing, harmonization, and clinician feedback to improve the quality of QCDR measures available for clinician reporting. These policies relate to CY 2020 and CY 2021 for QCDRs.
- As discussed in section III.K.3.c.(2)(b)(iii) of this proposed rule, we are proposing to add new episode-based measures in the cost performance category to more accurately reflect the cost of care that specialists provide. Further, we are proposing to revise the total per capita cost and the Medicare Spending Per Beneficiary (MSPB) measures in response to stakeholders' feedback suggestions.

While we continue efforts to strengthen the Quality Payment Program, we remain interested in clinician participation and engagement in the program. Finally, as the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, enacted February 9, 2018) extended the flexibility and transition years within the Quality Payment Program, we believe these proposed policies for Year 4 and our strategic vision will assist us in working towards a more robust program in the future.

(3) Major APM Proposals

(a) Aligned Other Payer Medical Home Models

We are proposing to add the defined term, Aligned Other Payer Medical Home Model, to § 414.1305. The proposed definition of Aligned Other Payer Medical Home Model includes the same characteristics as the definitions of Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. We believe that structuring this proposed definition in this manner is appropriate because we recognize that other payers could have payment arrangements that may be appropriately considered medical home models under the All-Payer Combination Option.

Neither the current Medical Home Model financial risk and nominal amount standards nor the Medicaid Medical Home Model financial risk and nominal amount standards apply to other payer payment arrangements. Consistent with our proposal to define the term Aligned Other Payer Medical Home Model, we are proposing to amend § 414.1420(d)(2), (d)(4), and (d)(8) of our regulations to also apply the Medicaid Medical Home Model financial risk and nominal amount standards, including the 50 eligible clinician limit, to Aligned Other Payer Medical Home Models.

(b) Marginal Risk for Other Payer Advanced APMs

We are proposing to modify our definition of marginal risk when determining whether a payment arrangement is an Other Payer Advanced APM. We propose that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual

[106] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[107] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.*

expenditures would be used for comparison to the marginal risk rate specified in with exceptions for large losses and small losses as described in § 414.1420(d). Average marginal risk would be computed by adding the marginal risk rate at each percentage of level to determine to determine participants' losses, and dividing it by the percentage above the benchmark to get the average marginal risk. When considering average marginal risk in the context of total risk, we believe that certain risk arrangements can create meaningful and significant risk-based incentives for performance and at the same time ensure that the payment arrangement has strong financial risk components.

(c) Estimated APM Incentive Payments and MIPS Payment Adjustments

As we discuss in section VI.E.10.a. of this proposed rule, for the 2022 payment year and based on estimated Advanced APM participation during the 2020 QP Performance Period, we estimate that between 175,000 and 225,000 clinicians will become Qualifying APM Participants (QPs). As a QP for the 2022 payment year, an eligible clinician is excluded from the MIPS reporting requirements and payment adjustment and qualifies for a lump sum APM Incentive Payment equal to 5 percent of their aggregate payment amounts for covered professional services for the year prior to the payment year. We estimate that the total lump sum APM Incentive Payments will be approximately $500–600 million for the 2022 Quality Payment Program payment year.

We estimate that approximately 818,000 clinicians would be MIPS eligible clinicians for the 2020 MIPS performance period in section VI.E.10.b.(1)(b) of this proposed rule. The final number will depend on several factors, including the number of eligible clinicians excluded from MIPS based on their status as QPs or Partial QPs, the number that report as groups, and the number that elect to opt into MIPS. In the 2022 MIPS payment year, MIPS payment adjustments, which only apply to payments for covered professional services furnished by a MIPS eligible clinician, will be applied based on a MIPS eligible clinician's performance on specified measures and activities within four integrated performance categories. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($584 million) and positive MIPS payment adjustments ($584 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance for MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 80 points that we are proposing in section III.K.3.e.(3) of this proposed rule. However, the distribution will change based on the final population of MIPS eligible clinicians for the 2022 MIPS payment year and the distribution of final scores under the program.

2. Definitions

At § 414.1305, we are proposing to define the following terms:

- Aligned Other Payer Medical Home Model.
- Hospital-based MIPS eligible clinician.
- MIPS Value Pathway.

We are additionally proposing to revise at § 414.1305 the following term:

- Rural area.

These terms and definitions are discussed in detail in relevant sections of this proposed rule.

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways Request for Information

(1) Overview

In this proposed rule, we are proposing to apply a new MIPS Value Pathways (MVP) framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. As discussed in section III.K.3.a.(3)(a) of this proposed rule, the MVP framework would be implemented as early as feasible to produce a MIPS program that more effectively meets the 7 strategic objectives described in the CY 2018 QPP final rule (82 FR 53570) and drives continued progress and improvement. The MVP framework would connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. As discussed in section III.K.3.a.(3)(a) of this proposed rule, we are proposing to apply this MVP framework to future proposals beginning with the 2021 MIPS performance period rather than the 2020 MIPS performance period, so that we can seek necessary feedback on the details of implementing this transformative approach and address additional details of the methodology in next year's rulemaking cycle. We understand that clinicians want timely performance feedback data on quality and cost to track their performance and prepare to take on risk, as required in Advanced APMs, and we intend to provide enhanced feedback and data analysis information to clinicians in the future. We plan to engage with clinician professional organizations and front-line clinicians to develop the MVPs.

(2) MVP Framework

(a) MVP Overview

We believe the MVPs will reduce the complexity of the MIPS program and the burden to participate. We intend to simplify MIPS while continuing to reward high value clinicians and help all clinicians improve care and engage patients. While we emphasized flexibility during the initial years of MIPS, we believe we must balance flexibility with a degree of standardization to hold clinicians accountable for the quality of care, identify and reward high value care, and limit clinician burden. Any solution to improving MIPS performance measurement data must account for the large variation in specialty, size, and composition of clinician practices. MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to the population they are caring for, a specialty or medical condition.

The MIPS program aims to drive quality and value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. For purposes of this discussion, we define ''value'' as a measurement of quality as related to cost, ''value-based care'' as paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care, and ''high value clinicians'' as clinicians that perform well on applicable measures of quality and cost. We believe implementing a ''path to value'' framework will transform the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes, and also by promoting robust and accessible healthcare data, and interoperability.

We are targeting policies that remove APM participation barriers as clinicians

and practices prepare to take on and successfully manage risk as practices build out their quality infrastructures with components that align with the MIPS performance categories. Critical practice infrastructure components that support higher value care and readiness to join APMs include performance measurement tracking, performance improvement processes, interoperability, and data information systems that assist clinicians and practices in monitoring performance and adopting new workflows and care delivery methods. Performance measure reporting for specific populations encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. For example, quality measurement can bolster the development of a practice infrastructure that rapidly integrates evidence-based best practices into the structure and execution of care delivery, to leverage a value-based payment, and to produce achievement of better health outcomes. Improvement Activities add a continuous clinical practice improvement component, that can help clinicians use the experiences and perspectives of front-line staff and beneficiaries to constantly assess, reconfigure, and innovate processes and systems of care delivery to better manage revenue and risk expenditure. Sensitivity to cost and experience with cost measures within a practice infrastructure is critical to managing value based payment and APM risk, while awareness of and sensitivity to cost from the beneficiary perspective (out-of-pocket cost, cost of time off from work for the patient and/or caregiver, cost of disruption of normal activities/relationships) can help support shared decision-making. An interoperability infrastructure component supports the development of a practice infrastructure that recognizes the critical role of information exchange in supporting safe, effective, and efficient coordination and transitions of care through a complex health care system, and better management of costs and risk. We believe that experience with MVPs, in which there is measurement of quality (of care and of experience of care) and cost-efficiency, continuous improvement/innovation within the practice, and efficient management and transfers of information, will remove barriers to APM participation.

We believe it is important to transform the MIPS program. We must change the current program to move along the path to value and enter a future state of MIPS, which includes a more cohesive and simplified participation experience for clinicians, increased voice of the patient, increased CMS provided data and feedback to clinicians to reduce reporting burden, and facilitated movement to Alternative Payment Models. Please refer to the on line MVP graphic (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/587/MIPS%20Value%20Pathways%20Diagrams.zip*) that provides an overview of our vision for the MIPS future state.

We have built the MIPS program recognizing the large variation in specialty, size, and composition of clinician practices, providing broad flexibility for clinician choice of measures and activities, data submission types, and individual or group level participation. Although we believe this flexibility contributed to Year 1 participation of 95 percent of MIPS eligible clinicians, including 94 percent of rural practices and 81 percent of small practices,[108] and the increase in Year 2 participation to 98 percent of MIPS eligible clinicians.[109] we also believe there is room to improve upon the program. Specifically, we believe this flexibility has inadvertently resulted in a complex MIPS program that is not producing the level of robust clinician performance information we envision providing to meet patient needs and spur clinician care improvements.

Although we have been reducing the numbers of MIPS quality measures in accordance with the Meaningful Measures initiative (*see* 83 FR 59763 through 59765), we have heard concerns from some stakeholders that MIPS presents clinicians with too much complexity and choice (for example, of several hundred MIPS and QCDR quality measures), causing unnecessary burden. As noted in the CY 2019 PFS final rule (83 FR 59720), we have received feedback that some clinicians find the performance requirements confusing, and that it is difficult for them to choose measures that are meaningful to their practices and have a direct benefit to beneficiaries.

We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due to clinician quality measures selection bias. This detracts from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. For example, in its June 2017 Report to Congress, MedPAC documented the need for changes to the MIPS program to increase clarity, reduce complexity, and make the burden of data submission worthwhile through higher impact. MedPAC recommended in their March 2018 Report to Congress using a uniform set of population-based measures for clinicians paid by Medicare who are not participating in an advanced APM, and provided an illustrative voluntary value model that used administrative claims and patient experience surveys. The MedPAC model did not include any specific clinical specialty or practice level measures.

We believe a hybrid approach is warranted—where clinicians are measured on a unified set of measures and activities around a clinician condition or specialty, layered on top of a base of population health measures, which would be included in virtually all of the MVPs. Over time, the information clinicians and groups are required to submit will be less burdensome and more meaningful to clinicians and patients. At the same time, we intend to analyze Medicare information to provide to clinicians and patients more information to improve the health of the Medicare beneficiaries. Finally, we anticipate capturing additional information important to patients. We envision applying this framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year as we integrate new MVPs, so that eventually, all MIPS eligible clinicians would have to participate through an MVP or a MIPS APM. We seek feedback on numerous elements related to the MVPs in sections III.K.3.a.(3)(a)(i) through III.K.3.a.(3)(a)(iv) of this proposed rule.

(b) Clinician Data Feedback

Clinicians have expressed an interest in leveraging data, such as timely claims data, to track performance and inform care improvements. We understand that performance data feedback on administrative claims-based quality and cost measures would potentially assist clinicians in understanding their performance and preparing to take on risk as required in Advanced APMs. We see the critical need for data feedback and intend to provide enhanced clinician driven data feedback and analysis information under the future MVP approach. We are interested in

[108] 2017 Quality Payment Program Reporting Experience, March 20, 2019 (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/491/2017%20QPP%20Experience%20Report.pdf*).

[109] Quality Payment Program (QPP) Participation in 2018: Results at a Glance, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/586/2018%20QPP%20Participation%20Results%20Infographic.pdf*.

whether clinicians would like to see outlier analysis or other types of actionable data feedback and are seeking comments on clinician data feedback content and timing needs in section III.K.3.a.(6) of this proposed rule.

(c) Enhancing Information for Patients

The MIPS program aims to drive quality and value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. We believe that our performance measurement should focus more on patient reported measures, including patient experience and satisfaction measures and clinical outcomes measures, as we believe that clinicians can use feedback from the patient perspective to inform care improvement efforts. We believe that MVPs should include patient reported measures when feasible. We believe implementing an MVP framework will transform the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians achieve better outcomes, and also by promoting robust and accessible healthcare data and interoperability.

We are dedicated to putting patients first and providing the information they need to be engaged and active decision-makers in their care. We believe that whenever feasible the MIPS program should provide meaningful information at the individual clinician level. We believe we need specific specialty information from multispecialty groups and are considering approaches to use the MVPs to require reporting relevant to multiple specialty types within a group to provide more comprehensive information for patients. We seek comment, as discussed in section III.K.3.a.(3)(b) of this proposed rule, on the best ways to identify which MVPs should be reported by multispecialty groups and how we should balance the need for information at the individual clinician level with the burden of reporting.

We are also looking at ways that we can gather and display information that is useful to patients. We are considering approaches, as discussed in section III.K.3.a.(6) of this proposed rule, to developing and reporting on Physician Compare a ''value indicator'' representing each clinician's performance on cost, quality, and the patient's experience of care. We are committed to learning more about the types of information patients use in making decisions and determining what information can be derived from the data reported or gathered as part of MIPS.

(3) Implementing MVPs

(a) MVP Definition, Development, Specification, Assignment, and Examples

We are seeking comments on the development and structure of MVPs, which would connect measures and activities across the quality, cost, and improvement activities performance categories. We believe that interoperability is a foundational element and thus would generally apply to all clinicians, regardless of the specific MVP, for whom the Promoting Interoperability performance category is required. MVPs would support our vision to measure value, reduce burden, simplify the MIPS performance measurement and scoring approaches, and ensure strong alignment of quality and cost measures. The four guiding principles we would use to define MVPs are:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.

2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.

3. MVPs should include measures that encourage performance improvements in high priority areas.

4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

We request public comments on the MVP guiding principles noted above. We also request public comments on how to best develop MVPs to allow for the development of better comparative data, reduce burden, and provide valuable information to patients and clinicians.

MVPs would be organized around clinician specialty or health condition and encompass a set of related measures and activities. We intend to ensure equity in MVPs so that clinicians are not advantaged by reporting one MVP over another (for example, in terms of reporting burden and scoring), but also want to include measures that have opportunities for improvement. Bundling quality and cost measures and improvement activities that are highly correlated in addition to the measures from the Promoting Interoperability performance category will strengthen clinical improvement and streamline reporting. As an initial step, we are proposing to require that beginning with the 2020 Call for measures process, MIPS quality measure stewards must link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. We refer readers to section III.K.3.c.(1)(d)(i) of this proposed rule for further discussion of our proposal.

We believe that MVPs can be created with significant input from clinicians and specialty societies, to ensure that measures and activities within MVPs are relevant and important to clinician practices. The most significant change with MVPs is that eventually all MIPS eligible clinicians would no longer be able to select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be connected around a clinician specialty or condition (*see* examples of potential MVPs in section III.K.3.a.(3)(a) of this proposed rule). We also intend that a population health measure/administrative claims-based measures would be layered into measuring the quality performance category, applied whenever there is a sufficient case minimum. Cost measures would be specific to the MVP and applied only when a clinician or group meets the case minimum. MVPs could potentially also allow for the use of multi-category measures, should they be developed, as clinician feedback has indicated there is an interest in the development of these performance measures that simultaneously address two or three of the MIPS performance categories (83 FR 35932).

As outlined in our goals for the Promoting Interoperability performance category in section III.K.3.c.(4)(b), we look to continue MIPS alignment with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, where appropriate. We envision Promoting Interoperability performance category measures, which focus on the meaningful use of certified EHR technology to support care coordination and electronic health information exchange, to be a key structural part of any MVP. Initially, there would be a uniform set of Promoting Interoperability measures in each MVP, though in future years we may consider customizing the Promoting Interoperability measures in each MVP. At this time, we are not considering making modifications to the Promoting Interoperability performance category as it becomes incorporated into the MVP framework. We believe that interoperability is a foundational element and thus would apply to all

clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required. However, we are seeking comment on how the Promoting Interoperability performance category could evolve in the future to meet our goal of greater cohesion between the MIPS performance categories. We believe that eligible clinicians could benefit from more targeted approaches to assessing the meaningful use of health IT which aligns with clinically relevant MVPs cutting across the MIPS performance categories. One approach we could consider is exploring which measures for the Promoting Interoperability performance category would be directly aligned with measures in other MIPS performance categories. For instance, many improvement activities are enabled by, or could be enabled by, the use of certified health IT including care coordination and patient engagement through health information exchange. We could develop Promoting Interoperability measures which measure the use of health IT in conducting these improvement activities, while relevant quality measures for a given MVP could assess quality outcomes associated with these activities. We invite comment on these concepts, as well as other suggestions for how the Promoting Interoperability performance category can be better integrated into MVPs.

We also believe that improvement activities can be closely linked to the quality and cost measures, to encourage improvement on performance of those measures. As clinicians report on a stable set of measures, there is an inherent incentive to change practice patterns to increase performance on required quality and cost measures. We are seeking feedback in section III.K.3.a.(3)(a)(ii) of this proposed rule on how many improvement activities should be included in an MVP and how much flexibility there should be in selecting improvement activities. We also seek feedback on the extent to which improvement activities in MVPs should be specialty-specific, condition-focused improvement activities, versus other areas relevant to the practice such as patient experience and engagement, team-based care, and care coordination. More generally, we would like to understand how improvement activities are used to improve quality measure performance within clinical practices.

Our goal in using MVPs is to standardize which measures and activities are reported, both to reduce clinician burden and better measure performance among comparable clinicians while appropriately recognizing the variability of clinician practices and potentially reducing barriers to moving into APMs, which generally measure quality for their respective participants using the same quality measures. We can also look to APMs for methods of linking quality and value measurement as APMs are designed around value, and address quality, cost, and care redesign for a specific population.

We realize that there are numerous issues on which we need stakeholder feedback to fully implement MVPs, but we believe the basic approach could start in the 2021 MIPS performance period/2023 MIPS payment year. We are requesting public comments on the following issues:

- How to construct MVPs, including approach, definition, development, specification, and examples referenced at III.K.3.a.(3)(a)(i) of this proposed rule;
- How to select measures and activities for MVPs, referenced at III.K.3.a.(3)(a)(ii) of this proposed rule;
- How to determine MVP assignment, referenced at III.K.3.a.(3)(a)(iii) of this proposed rule; and
- How to transition to MVPs, referenced at III.K.3.a.(3)(a)(iv) of this proposed rule.

To begin implementing MVPs, we are proposing to define a MIPS Value Pathway at § 414.1305 as a subset of measures and activities specified by CMS. We anticipate that MVPs may include, but would not be limited to, administrative claims-based population health, care coordination, patient-reported (which may include patient reported outcomes, or patient experience and satisfaction measures), and/or specialty/condition specific measures. MVPs would include a population health quality measure set, and measures and activities such that all 4 MIPS performance categories are addressed, and each performance category would be scored according to its current methodology. Under MVPs, the current MIPS performance measure collection types would continue to be used to the extent possible, but these details need to be worked out and would be addressed in next year's rulemaking cycle. We request comment on performance measure collection types for MVPs in section III.K.3.a.(3)(a)(ii) of this proposed rule.

We provide 4 illustrative examples of MVPs in Table 34. The examples demonstrate how MVPs could be constructed and show the types of measures and activities that might be assigned to each MVP. We present 2 example MVPs for primary care and general medicine, which includes preventive health and diabetes prevention and treatment, as well as two example MVPs for procedural specialties, which include major surgery and general ophthalmology. Within our sample MVPs, we present no more than 4 quality or cost measures or improvement activities for each performance category. However, the exact number of measures and activities could vary across MVPs. We envision that we would no longer require the same number of measures or activities for all clinicians but focus on what is needed to best assess the quality and value of care within a particular specialty or condition. To assign quality measures in these examples, we prioritized outcome and patient reported measures, non-topped out measures, and eCQMs. To assign cost measures, we reviewed existing measures and selected those that fit into the MVP topic. We also included population health measures, which are described in section III.K.3.a.(4) of this proposed rule. We reviewed and selected relevant improvement activities that align with the quality and cost measures in the MVPs. We are interested in feedback on whether improvement activities should focus on improving the quality and cost measures within an MVP or be much broader including any improvement activities that are relevant to the practice. We are interested in exploring approaches to leverage participation in specialty accreditation programs, such as the American College of Surgeons' Commission on Cancer accreditation program. Since specialty accreditation programs may promote the evaluation and improvement of clinical processes and care, we believe it may be appropriate to incorporate attestation to participation in such programs as an approach to satisfy the requirements of the improvement activities performance category, for example, by proposing to specify such participation as an improvement activity for all MVPs or specific MVPs in future rulemaking. To align with the statutory requirement that a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice be given the highest potential score for the improvement activities performance category, we have also included an illustrative example under the Preventive Health MVP to depict how patient-centered medical homes or comparable specialty practices would receive credit under the improvement activities performance category. We anticipate that all measures in the Promoting Interoperability performance category would initially be applicable to

each MVP unless an exclusion applies; thus, we assigned all Promoting Interoperability measures to all MVPs. We welcome comments on the examples of possible MVPs and on options for encouraging interoperability to promote improvements in care and performance measurement results.

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TABLE 34: Examples of Possible MIPS Value Pathways

MVP Example	Quality Measures	Cost Measures	Improvement Activities**	Promoting Interoperability
Preventive Health	• Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID: 226) • Osteoarthritis: Function and Pain Assessment (Quality ID: 109) Adult Immunization Status, proposed (Quality ID: TBD) • Controlling High Blood Pressure (Quality ID: 236) • PLUS: population health administrative claims quality measures (e.g., all-cause hospital readmission)	• Total Per Capita Cost (TPCC_1) • Medicare Spending Per Beneficiary (MSPB_1)	• Chronic Care and Preventive Care for Empaneled Patients (IA_PM_13) • Engage patients and families to guide improvement in the system of care (IA_BE_14) • Collection and use of patient experience and satisfaction data on access (IA_EPA_3)	• All measures in Promoting Interoperability***
Diabetes Prevention and Treatment	• Hemoglobin A1c (HbA1c) Poor Care Control (>9%) (Quality ID: 001) • Diabetes: Medical Attention for Nephropathy (Quality ID: 119) • Evaluation Controlling High Blood Pressure (Quality ID: 236) • PLUS: population health administrative claims quality measures	• Total Per Capita Cost (TPCC_1) • Medicare Spending Per Beneficiary (MSPB_1)	• Glycemic Management Services (IA_PM_4) • Chronic Care and Preventative Care Management for Empaneled Patients (IA_PM_13)	• All measures in Promoting Interoperability ***
Major Surgery	• Unplanned Reoperation within the 30-Day Postoperative Period (Quality ID: 355) • Surgical Site Infection (SSI) (Quality ID: 357) • Patient-Centered Surgical Risk Assessment and Communication (Quality ID: 358) • PLUS: population health administrative claims quality measures	• Medicare Spending Per Beneficiary (MSPB_1) • Revascularization for Lower Extremity Chronic Critical Limb Ischemia (COST_CCLI_1) • Knee arthroplasty (COST_KA_1)	• Use of patient safety tools (IA_PSPA_8) • Implementing the use of specialist reports back to referring clinician or group to close referral loop (IA_CC_1) OR • Completion of an Accredited Safety or Quality Improvement Program (IA_PSPA_28)	• All measures in Promoting Interoperability ***
General Ophthalmology	• Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Quality ID: 012) • Diabetic Retinopathy: Communication with Physician Managing Ongoing Diabetes Care (Quality ID: 019)	• Medicare Spending Per Beneficiary (MSPB_1) • Routine Cataract Removal with Intraocular Lens Implantation (COST_IOL_1)	• Implementation of improvements that contribute to more timely communication of test results (IA_CC_2) • Comprehensive eye exam (IA_AHE_7)	• All measures in Promoting Interoperability ***

	• Cataracts: 20/40 or Better Visual Acuity within 90 days Following Cataract Surgery (Quality ID: 191) • PLUS: population health administrative claims quality measures			

*Measures and activities selected for illustrative purposes and are subject to change.

**Recognized or certified patient-centered medical homes or comparable specialty practices could participate in an MVP and still receive credit for the improvement activity performance category.

***See Table 41 in section III.K.3.c.(4)(d)(ii)(B) for the Promoting Interoperability measures.

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The examples in Table 34 are illustrative only, but we envision that we would start building MVPs by reviewing the existing specialty measure sets for the quality performance category. However, some specialty measure sets contain multiple conditions or concepts, so we do not envision a one-to-one correlation between the specialty measure sets and MVPs.

We anticipate that eventually many clinicians would have at least one relevant MVP, while other clinicians may have several. In particular, we believe that multispecialty groups will have more than one relevant MVP. If technically feasible, we would like to establish a methodology that allows us to identify and assign in advance the relevant MVP(s) for MIPS eligible clinicians or groups and require the clinician or groups to report on those MVPs. In addition, we would consider folding MIPS APM measures and activities into MVPs and develop an assignment process as described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), applying a hierarchy which applies APM entity final scores over any other final score.

We are interested in feedback on the level of choice that should be provided to clinicians for MVP selection or selection of measures and activities within an MVP. We have heard from some clinicians that they would prefer a clear list of what specific measures and activities they have to perform versus various options of measures and activities to report. We believe a methodology in which clinicians are informed of the potential MVP(s) that are available for a clinician or group to report on would be simpler to communicate and allow for both clinicians and CMS to better understand what measures and activities should be submitted. We are considering assigning MVPs to clinicians and groups, if technically feasible, starting with the 2021 MIPS performance period as MVPs become available and would propose the MVP assignment process in next year's rulemaking cycle. We are considering the feasibility of potential data sources or methods to use to assign clinicians to an MVP, such as the specialty reported on Part B claims or use of Medicare Provider Enrollment, Chain, and Ownership System (PECOS) data. We seek comment on circumstances when we should allow clinicians and groups to select an alternative MVP, rather than the one or more MVP(s) assigned. Those clinicians and groups who would not have an applicable MVP for the 2021 MIPS performance period would continue the current process of reporting MIPS measures and activities for the 4 performance categories. As an alternate option, we could consider self-assignment of MVPs for the 2021 MIPS performance year period with the intention of assigning MVPs to clinicians starting in the 2022 MIPS performance period. Clinicians have had flexibility in choosing MIPS quality measures to date, and we expect retaining a degree of choice will be welcome by some clinicians as we transition to MVPs. We anticipate that the number of available MVPs would increase in the 2022 MIPS performance period and subsequent years, which would allow for MVP assignment for all clinicians and groups. We are requesting public comments on whether clinicians and groups should be able to self-select an MVP or if an MVP should be assigned. If assigned, we are requesting comments on the best way to assign an MVP—should it be based on place of service codes, specialty designation on Part B claims, or in the case of groups, should the assigned MVP(s) be based on the specialty designation of the majority of clinicians in the group, specific services, or other factors?

We are considering approaches to assigning MVPs to multispecialty groups to be inclusive of the different specialties providing care to patients. Alternatively, we are also considering approaches that would allow for self-assignment of MVPs where multispecialty groups would select one or more MVPs that are most relevant to the specialty mix within the group.

We believe the approach to MVPs must find the right balance between having a sufficient number of MVPs to allow clinicians to report on measures and activities relevant to their practices, without developing so many MVPs that reporting is diluted and developing benchmarks is hampered. For example, we would not want to have several MVPs for the same specialty or condition because then only a portion of the MIPS eligible clinicians are reporting on the quality measures, which limits the ability to develop benchmarks and to make meaningful comparisons of clinicians.

In addition, due to differences in collection types for many quality measures, we can have multiple benchmarks for each measure, which further complicates the ability to make meaningful comparisons. The diversity of MVPs and collection types of quality measures may hamper MIPS in meeting its vision of effectively measuring and comparing performance, providing meaningful feedback, incentivizing quality, and providing patients with enhanced information for making clinician selection choices.

We believe Electronic Clinical Quality Measures (eCQMs) have the potential to decrease reporting burden within MVPs. Stakeholders have previously supported eCQMs and the associated reduction in information collection burden under a variety of CMS programs and have made recommendations for improving eCQMs (83 FR 41593). While we support the reporting of eCQMs through the MIPS program, we have identified certain eCQMs for removal. We may propose to remove measures that are extremely topped out, duplicative of a new measure, or are low-adopted measures that have been in the program for 2 or more years. We refer readers to Table Group C of Appendix 1 for the list of previously finalized quality measures proposed for removal in the 2022

payment year. Through our Call for Measures process, and related measure development resources, such as the CMS BluePrint at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* and the CMS Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2018-MDP-annual-report.PDF*, we encourage stakeholders to submit electronically specified measures for CMS consideration. We recognize that there are challenges related to development of new eCQMs and technical aspects, however, we are interested in eCQMs and their potential use in MVPs to reduce reporting burden. For further discussion of strategies for reducing burden associated with reporting eCQMs, refer to the Office of the National Coordinator for Health Information Technology draft report, *Strategy of Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* (*https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf*).

We are interested in feedback on our timeframe for transitioning into MVPs. We anticipate that we will have a number of MVPs proposed for the 2021 MIPS performance period. However, we understand that there are many operational considerations that should be taken into account. We request comment on approaches to accelerate the development and implementation of MVPs, as well as any comments on the optimal timeline for transition.

Over the next year, we may consider convening public forum listening sessions, webinars, and office hours, or use additional opportunities such as the pre-rulemaking measures process to understand what is important to clinicians, patients, and stakeholders, as we develop MVPs.

(i) Request for Feedback on MVP Approach, Definition, Development, Specification, Assignment, and Examples

We are requesting public comments on how MVPs are developed.

- We have stated MVP guiding principles regarding reducing burden, providing comparative performance data to patients and caregivers, encouraging improvements in high priority areas, and reducing barriers to APM participation. Should we consider other guiding principles as we define and develop MVPs?
- In addition to gathering feedback from this proposed rule, how do we best engage stakeholders in the development of MVPs?

++ How would stakeholders like to be engaged in MVP development? What type of outreach would be the most effective in gathering the voice of the patient in the MVP concept and the selection of measures?

++ For quality measures, should we initiate a ''Call for MVPs'' that aligns with policies developed for the Call for Measures and Measure Selection Process, described in section III.K.3.c.(1)(d)(i) of this proposed rule, or should we use an approach similar to the process used to solicit recommendations for new specialty measure sets and revisions to existing specialty measure sets, as described in section III.K.3.c.(1)(d)(i) of this proposed rule?

- How should MVPs be organized, for example, around specialties and areas of practice? Alternatively, should MVPs be organized to address a small number of public health priorities, for example, HIV care or healthcare-associated infections? Please refer to Table 34 for examples of specialty MVPs.
- How can we ensure the right number of MVPs that result in comparable and comprehensive information that is meaningful for the clinicians, patients, and the Medicare program? How should we limit the number of MVPs? Should each specialty have a single MVP?
- How should we build on Promoting Interoperability, a foundational component of MVPs, as we link the 4 categories within MVPs? How could we best promote the use of health information technology and interoperability in practices not yet using electronic health records?
- How can MVPs effectively reduce barriers to clinician movement into APMs, such as practice inexperience with cost measurement and lack of readiness to take on financial risk?

(ii) Request for Feedback on Selection of Measures and Activities for MVPs

We are requesting public comments on the selection of measures and activities in MVPs.

- Please provide feedback on the Example MVPs in Table 34 that might help us in our development of additional MVPs. In the example, there is a list of required quality measures and improvement activities. Should MVPs include only required measures and activities, or a small list of quality measures and activities from which clinicians could choose what to report?
- What criteria should be used for determining which measures and activities should be included in an MVP, such as prioritizing outcome, high priority and patient-reported measures; limiting the number of quality measures to 4, including only cost measures that align with quality measures, etc.? How should performance categories and associated measures and activities be linked (*e.g.,* quality measures aligned with cost measures)?
- For the quality measures, should clinicians and groups be required to use a certain collection type (eCQMs, MIPS Clinical Quality Measures [MIPS CQMs], CMS Web Interface, or QCDR measures) in order to have a comparable data set in the MVPs? What will clinicians' administrative burden be for changing to a new, specific collection type for a measure, for example, changing from MIPS CQM to an eCQM?
- Currently we have similar measures addressing the same clinical topic, with different collection types (for example, eCQMs, MIPS CQMs, QCDR measures, etc.) that have different specifications and separate benchmarks. What methodology could be used to develop a single benchmark when multiple collection types are used? Another solution we may consider to ensure comparable measure data and request feedback on is to require a single collection type. Please also refer to section III.K.3.a.(3)(c) of this proposed rule for more about QCDR measures in MVP.
- Should improvement activities in MVPs be restricted to activities directly related to the clinical outcomes of the quality and cost measures in the MVP, for example, IA_PM_4 ''Glycemic Management Services'' for a Diabetes MVP, or should the selection of improvement activities include cross-cutting activities, for example, IA_EPA_1 Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record? Should attestation to participation in a specialty accreditation program satisfy the improvement activities performance category requirements for an MVP? Should this option be available for all MVPs or limited to specific MVPs, such as particular specialties for which accreditation programs are available? What criteria should we use to identify such programs?

(iii) Request for Feedback on MVP Assignment

We are requesting public comments on how we determine the most relevant MVP for clinicians and groups.

• How should we identify which MVP(s) are most appropriate for a clinician? Would it be based on the clinician specialty as identified in PECOS or the specialty reported on claims? If we assign an MVP, how would we be able to verify the applicability of the assigned MVP?

• Should we provide clinicians and groups more than one applicable MVP and allow clinicians to select their MVP(s) from those identified? What tools would be helpful for clinicians to understand what MVP(s) might be applicable, for example NPI lookup, measure shopping cart, etc.?

(iv) Request for Feedback on Transition to MVPs

We are requesting public comments on how we transition to MVPs beginning with the 2021 MIPS performance period/2023 MIPS payment year.

• What practice level operational considerations do we need to account for in the timeline for implementing MVPs?

(b) Adjusting MVPs for Different Practice Characteristics

(i) Small and Rural Practices Participation in MVPs

We realize that reporting burden associated with MIPS can vary by the size of the practice. Under current quality performance category submission requirements, the same number of measures and activities are reported regardless of group size, which may impose a high burden on small practices, given their very limited resources to address program requirements. Another challenge for small and rural group practices is the lack of a sufficient case mix to report measures that can be reliably scored, which makes the use of a set of administrative claims-based quality and cost measures especially challenging. Policies for submission of measures and scoring for MVPs may need to account for these challenges. As we move towards MVPs, we will be evaluating other policies (such as eligibility requirements, including the low-volume threshold (§ 414.1305), submission requirements (§ 414.1325), scoring (§ 414.1380), etc.) for further modification.

We also want to adopt policies that reduce barriers for small practices transitioning into APMs where available. We have seen that there are innovative small groups including over 83,000 clinicians (in small practices with less than 4 clinicians) that joined the Transforming Clinical Practice Initiative (TCPI) Practice Transformation Networks (PTNs), who followed tailored, targeted and disciplined practices, and transitioned into advanced practices, for example, practices that met APM readiness milestones in their practice assessments and considers itself ready for migrating into an alternative based payment arrangement. Presently, there are a total of 60,311 clinicians that have transitioned to APMs. Within TCPI, these APMs, in alignment with the CMS Healthcare Payment Learning and Action Network APM Framework, are Category 3 (APMs Built on Fee For-Service Architecture) and Category 4 (Population-Based Payment) payment arrangements.[110] We understand that there are certain factors that enable clinicians to make the transition into APMs, including the readiness to take on additional risk, the ability to use timely feedback to make practice changes, willingness to engage in peer-to-peer learning and community of practices, accessing technical assistance, and an ability to invest in infrastructure to enable care improvement and efficiencies. Developing MVPs in alignment with APM measures may assist small practices by providing experience with some APM requirements, and enhanced CMS feedback data on quality and cost performance can help clinicians make practice improvements and increase readiness to participate in Advanced APMs.

(A) Request for Feedback on Small and Rural Practices Participation in MVPs

We are requesting public comments on policies to support small practices.

• How should we structure the MVPs to provide flexibility for small and rural practices and reduce participation burden? What MVP related policies could best assist small and/or rural groups when submitting measures and activities? Should we have alternate measures and activities submission requirements for small and/or rural practices? For example, should small and/or rural practices be allowed to report fewer measures and activities within an MVP?

• How can we mitigate challenges small and/or rural practices have in reporting? What types of technical assistance would be most helpful to help small and/or rural practices to have successful participation in MVPs?

• How can we reduce barriers to small and/or rural groups to transitioning into APMs, such as lack of information on performance on quality and cost measures and limited resources? What approaches could help small practices transition to MVPs?

(ii) Multispecialty Practices Participation in MVPs

At § 414.1305, a group is defined as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. Section 1848(q)(1)(D)(ii) of the Act requires that the MIPS process, for assessing group practices, must to the extent practicable reflect the range of items and services furnished by the MIPS eligible clinicians in the group practice involved. Multispecialty groups, especially those groups with a large number of clinicians, often provide an array of services that may not be captured in a single set of measures or in a single MVP. We have also heard similar concerns from stakeholders. In the CY 2019 PFS proposed rule (83 FR 35891), we acknowledged one of the overarching themes we have heard from stakeholders is that we make an option available to groups that would allow a portion of a group to report as a separate sub-group on measures and activities that are more applicable to the sub-group and be assessed and scored accordingly based on the performance of the sub-group. We solicited comment on specific options and questions for implementation of sub-group level reporting in future years in response to some stakeholders who requested the ability to report quality data for a portion of a TIN so that they can report measures and activities more relevant to their practice. However, as we noted in the CY 2019 PFS final rule (83 FR 59742), because there are numerous operational challenges with implementing such a sub-group option, we did not propose any such changes to our established reporting policies regarding the use of a sub-group identifier. In the CY 2018 Quality Payment Program final rule (82 FR 53593), we stated that in future rulemaking we intend to explore the feasibility of establishing group-related policies that would permit participation in MIPS at a sub-group level and create such functionality through a new identifier.

As we consider this transition to MVPs, we are seeking public comment on whether we can use the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by the group practice. This approach could address

[110] *http://hcp-lan.org/workproducts/apm-framework-onepager.pdf.*

stakeholder concerns about reporting on meaningful measures which are related to their practice without adding undue operational and data collection burden associated with creating and maintaining identifiers for sub-groups. Under this approach, multispecialty groups would report on multiple assigned or selected MVPs, where assignment or selection of MVPs would be proposed in future rulemaking, at the group level. Depending on how the MVPs are then combined and scored at the group level, this may eliminate the need for groups to create sub-TIN identifiers and apply eligibility criteria at the sub-TIN level.

We are interested in developing criteria to identify which MVPs are applicable to multispecialty groups and whether or not we should require the reporting of multiple MVPs. Such an approach would provide patients with better information about care and services provided by multispecialty groups. If we require reporting on more than one MVP, we may consider putting a cap on the number of MVPs, measures, and activities to ensure there is no undue burden for multispecialty practices. We are interested in how to improve both large and small multispecialty group reporting of MIPS performance measures and activities.

(A) Request for Feedback on Multispecialty Practices Participation in MVPs

We are requesting public comments on MVP policies for multispecialty practices.

- We are considering a requirement in future years that multiple specialty types within a group report relevant MVPs to provide more comprehensive information for patients. We are seeking comment on whether we can use the MVP approach as an alternative to sub-group reporting to more comprehensively capture the range of the items and services furnished by the group practice. For example, would it better for multispecialty groups to report and be scored on multiple MVPs to offer patients a more comprehensive picture of group practice performance or for multispecialty groups to create sub-groups which would break the overall group into smaller units which would independently report MVPs? How should we balance the need for information for patients on clinicians within the multispecialty practice with the clinician burden of reporting?
- What criteria should be used to identify which MVPs are applicable to multispecialty groups? For example, should it be based on the number or percentage of clinicians from the same specialty in the group? Should a group be able to identify which clinicians will report which MVP?
- Should there be a limit on the number of MVPs that could be reported by a multispecialty group?
- What mechanisms should be used to assess a group's specialty composition to determine which MVPs are applicable? For example, would groups need to submit identifying information to assure that measure MVPs aligned with the number or percent of clinicians of different specialties within a group? Is there information (such as specialty as identified in PECOS or the specialty reported on claims) we could leverage to ensure the appropriateness of MVPs for groups?
- In section III.E.1.c. of this proposed rule, we seek public comment on whether to align Shared Savings Program quality reporting requirements and quality scoring methodology with MIPS. As MIPS transitions to MVPs and addresses multispecialty practices, What MVP policies should be applied to MIPS APM participants?

(c) Incorporating QCDR Measures Into MVPs

As part of our path to value focus, we want participation in MIPS to become more meaningful to patients and clinicians. QCDR measures are not included in our proposals for annual rulemaking and are separate from MIPS measures, which are finalized through the rulemaking process. We refer readers to section III.K.3.g.(2)(c) of this rule for discussion of proposals to strengthen QCDR measures.

Both QCDR and MIPS measures are currently available for clinicians to choose from to fulfill the requirements under the quality performance category. We have been encouraged by clinician adoption of QCDRs and their measures in the time since the Quality Payment Program became operational. Clinicians are interested and dedicated to quality improvement and have worked with QCDRs to foster an innovative and flexible approach to quality measurement and improvement. We continue to believe that participation in these QCDR quality improvement programs is a strong sign of a commitment to quality and improvement.

While this environment has encouraged a flexible approach to quality improvement, we believe it has also contributed to confusion and lack of consistency in measurement as our list of MIPS measures is greatly outpaced by the number of QCDR measures.

As noted in section III.K.3.a.(3)(a) of this rule, we are considering a major change in the submission requirements for MIPS eligible clinicians beginning with the 2021 MIPS performance period. We believe that a smaller and more focused set of quality measures assembled into an MVP, integrated with cost measures and improvement activities, will better serve the program by reducing the complexity of identifying how to participate in the program for clinicians, improving our ability to compare clinicians, and improving beneficiaries' ability to identify high quality practices. A proliferation of measures that are different for every modest variation in practice is contrary to such a goal. Therefore, we need to consider the role of QCDR measures in such an environment.

(i) Request for Feedback on Incorporating QCDR Measures Into MVPs

We are requesting public comments on policies for how QCDR measures would be used in MVPs:

- Should QCDR measures be integrated into MVPs along with MIPS measures, or should they be limited to specific MVPs consisting of only QCDR measures? How do we continue to encourage clinicians to use QCDRs under MVPs?

(d) Scoring MVP Performance

As we are proposing to apply the MVP framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year, we may propose scoring changes in future rulemaking. We anticipate that our basic approach to scoring measures and activities would remain stable with MVPs. In particular, we believe that both quality and cost performance category measures within MVPs would be scored using a scale of 0 to 10 and performance assessed by comparing to a benchmark, using the current approach to calculate benchmarks. We refer readers to sections III.K.3.c.(1)(b) and III.K.3.c.(2)(a) of this proposed rule for further discussion on how the quality and cost performance categories respectively contribute to the final score. For quality measures, we anticipate, when possible, that MVPs would use a single benchmark for each measure and that all clinicians and groups in the MVP would be compared against the same standard. In addition, we would no longer need special scoring policies and bonuses to incent selection of certain measures because clinicians would be required to report

all measures and activities in the MVP. Finally, we could align improvement scoring for quality and cost performance measures, because clinicians would use a stable set of measures, allowing for comparison year-to-year at the measure level. We believe the standardized sets of measures in MVPs would enable us to smoothly integrate new measures and collect data to develop robust benchmarks before scoring these measures on performance. We believe that scoring under the MVPs will potentially reduce barriers to clinicians' movement into APMs, which generally score their respective participants using the same quality measures and strongly align quality and cost measures.

We believe that small practices will continue to face challenges with meeting case minimums that allow reliable scoring of quality measures. Our scoring policies will need to take into account that not all measures reported by small practices can be scored based on the case mix available for reporting.

We anticipate that the underlying scoring framework for scoring improvement activities referenced in III.K.3.d.(1)(d) of this proposed rule would not change for clinicians; however, there could be the potential to better link cost and quality measures and the associated improvement activities. We do not anticipate that the underlying framework for scoring Promoting Interoperability measures referenced in III.K.3.d.(1)(e) of this proposed rule would change because of the introduction of the MVP framework. Promoting Interoperability is a foundational component of MVPs. Scoring policies may be developed as more details of the implementation of MVPs are developed.

We would also consider proposing scoring policies to evaluate MVPs holistically, making sure that scoring across MVPs is equitable and that clinicians are not unfairly advantaged by reporting a specific MVP. We seek feedback on scoring policies that will help us create level comparability across MVPs.

Additionally, if we propose in the future to allow or require multispecialty groups to submit more than a single MVP of measures and activities, we would need to develop scoring policies to fairly score such groups.

(i) Request for Feedback on Scoring MVP Performance

We are requesting comments on the following:

- What scoring policies can be simplified or eliminated with the introduction of MVPs? For example, we may consider eliminating scoring available for 2021 MIPS performance period providing a 3-point floor for each submitted measure that can be reliably scored (83 FR 59842). Additionally, we may consider eliminating the scoring bonuses available for the 2021 MIPS performance period for submitting high-priority measures and use of CEHRT to support quality performance category submissions (83 FR 59850 to 59852). Are there other scoring policies that could be simplified or eliminated?
- We seek feedback on scoring policies that will help us create level comparability across MVPs. Are there approaches we should take to create equity across MVPs and across clinician types, for example, that regardless of the number of measures and activity, no single MVP would ''outperform'' others? For example, should there be an MVP adjustment added to the performance category scores?
- How should we score multispecialty groups reporting multiple MVPs? Should scores be consolidated for a single group score or scored separately (and with separate MIPS payment adjustments) for specialists within the group? Alternatively, should we have an aggregate score for the multispecialty group?

(4) MVP Population Health Quality Measure Set

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures, for purposes of the MIPS quality performance category. Currently, the MIPS program has one administrative claims-based quality measure, the all-cause readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum (81 FR 77300). In the CY 2019 PFS proposed rule (83 FR 59719), we discussed our intent to use the Meaningful Measures Initiative within the Quality Payment Program to help address clinician reporting burden and improve patient outcomes through MIPS performance measurement. The Meaningful Measures Initiative represents an approach to quality measures that fosters operational efficiencies, reduces costs associated with collection and reporting burden, and produces quality measurement focused on meaningful outcomes. As we apply the Meaningful Measures framework within MIPS to reduce reporting burden and strengthen the use of measures that matter to patients and clinicians, we are considering how to implement a population health administrative claims-based quality measure set.

Global or population quality measures calculated from administrative claims-based quality data can be used as a foundational measure set to help improve patient outcomes, reduce data reporting burden and costs, better align clinician quality improvement efforts, and increase alignment with APMs and other payer performance measurement. The April 2019 Health Care Payment Learning & Action Network's *Roadmap for Driving High Performance in Alternative Payment Models* (*https://hcp-lan.org/workproducts/roadmap-final.pdf*), intended as a tool to begin identifying promising practices for implementing successful APMs, points out that:

- Payers use HEDIS® quality measures along with administrative claims-based quality measures, such as preventable admissions and readmissions, in designing ACOs and primary care model APMs
- Providers are more likely to participate in APMs if the required measures align with measures they already track (*see* Roadmap page 19), and
- There is room for improvement in the area of quality measurement to meaningfully assess health and quality-of-life outcomes (*see* Roadmap page 60).

We believe an administrative claims-based quality measure set consisting of a small number of quality measures focused on outcomes and intermediate outcomes can move MIPS towards population health measurement.

We have heard from some stakeholders that we should drive quality measurement towards a set of population-based outcome measures. We believe increasing the number of population health measures that utilize administrative claims data in the MIPS program while reducing the number of required condition and specialty specific measures would reduce the burden associated with quality reporting. However, we recognize that the use of an administrative claims-based quality measure set would entail certain tradeoffs. These measures historically have been applicable to primary care clinicians, with less relevance for some specialists. They have also been limited to Medicare fee for service patients, excluding other payer patients, and therefore, have not provided a picture of a clinician's entire practice and patient base. In addition, administrative claims-based quality measures require a large sample to produce reliable results, which presents challenges in a clinician program that allows for participation by individuals

and groups with relatively few patients in a specific measure denominator. However, given the opportunity to reduce burden (because clinicians do not need to report the administrative claims-based quality measures themselves), apply measures across different clinician types, focus on important public health priorities, and reduce barriers to APM participation, we want to find ways to effectively use administrative claims-based population health quality measures in MIPS.

We are working on multiple fronts to find the best and most appropriate measures for the MIPS program. For example, we are working with measure stewards on technical specifications to ensure the measures are reliable and broadly applicable to MIPS eligible clinicians. We intend to have the measures reviewed by a consensus-based entity, for example, the National Quality Forum (NQF) Measure Applications Partnership (MAP). We have looked at the use of administrative claims-based quality measures in the Shared Savings Program and the Comprehensive Primary Care Plus (CPC+) model to identify examples of measures that could be included as MIPS measures. As one example, in addition to an all-cause readmission measure (similar to the one currently used in MIPS), the Shared Savings Program has a measure (ACO—38), the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions, that we are in the process of adapting and testing for the MIPS program. In section III.K.3.c.(1)(d)(ii) of this proposed rule, we are proposing to add All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure to MIPS for the 2021 MIPS performance period. The Shared Savings Program also has a risk adjusted measure, (ACO—43), the Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91), which assesses the risk adjusted rate of hospital discharges for acute PQI conditions with a principal diagnosis of dehydration, bacterial pneumonia, or urinary tract infection among ACO assigned Medicare fee-for-service (FFS) beneficiaries 18 years and older. In section III.E.1.b., we recognize that the measure steward, AHRQ, has made ''substantive'' change to the measure and propose to redesignate ACO—43 to a pay-for-reporting measure for the 2020 and 2021 performance years, while seeking comment on other approaches including developing historic benchmarks.

As we work to improve and develop a foundational population health quality measure set, we are reviewing measures that we could propose in future rulemaking. We are reviewing whether it would be appropriate to add a measure similar to the ACO—43 Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) to MIPS. We are also reviewing two risk adjusted utilization measures that are included in the CPC+ Model Quality and Utilization Measure Set for the 2019 Performance Period for potential inclusion in the MIPS program: The HEDIS® Acute Hospital Utilization (AHU) (this is the inpatient hospital utilization measure in CPC+ Model that was updated by NCQA in 2018); and the HEDIS® Emergency Department Utilization (EDU).[111] These measures assess the risk-adjusted ratio of observed-to-expected acute inpatient and observation stay discharges during the measurement year reported by surgery, medicine and total among members 18 years of age and older. These measures are currently specified for health plans, but we intend to work with the measure steward, NCQA, for appropriateness for the MIPS program.

Clinicians raised concerns in response to previously proposed administrative claims-based quality measures. These concerns included measure reliability and applicability case size, attribution, risk adjustment, application at the clinician or group level, and degree of actionable feedback for improvements (81 FR 77130 through 77136). We finalized use of the all-cause readmission measure but limited its applicability to groups of 16 or more clinicians with a minimum of 200 cases to mitigate some of the concerns. We did not finalize the proposed AHRQ Acute Conditions Composite and Chronic Conditions Composite measures (81 FR 28192 and 28447). Our intention is to address the technical challenges as we test the Ambulatory Sensitive Condition Acute Composite measure and present to a consensus-based entity (for example NQF) to ensure the measure is reliable. We seek feedback on additional steps to ensure the measure addresses the concerns noted above.

Clinician feedback also called for the examination of potential sociodemographic status risk adjustment for administrative claims-based quality measures. Please refer to section III.K.3.d.(2)(a) of this proposed rule for information on our approach to accounting for risk factors in MIPS, including the complex patient bonus which was finalized for the 2020 MIPS payment year (82 FR 53771 through 53776), as well as plans to take into consideration a second report by ASPE expected in October 2019 on accounting for risk factors in quality, resource use and other measures in Medicare. We are proposing to continue the complex patient bonus in MIPS and would continue to assess the need for and effectiveness of such a scoring adjustment to ensure fair performance comparisons between clinicians.

In summary, we plan to increase the use of global and population based administrative claims-based quality measures as we develop a population health quality measure set and are outlining our proposal to add at least one additional administrative claims-based quality measure starting in the 2021 MIPS performance period in section III.K.3.c.(1)(d)(ii) of this proposed rule.

(a) Request for Feedback on Population Health Quality Measure Set

We are requesting public comments on the use of a population health quality measure set.

- In addition to the quality measures described above, are there specific administrative claims-based quality measures we should consider, including, but not limited to, any that assess specialty care that are specified and/or tested at the clinician/group practice level?
- We would like to balance the desire for quality measures specific to a clinical practice with a reduction in administrative burden for submission. Should administrative claims-based quality measures be used to replace some of the reporting requirements in the quality performance category? For example, if two additional administrative claims-based quality measures were added to MVPs should we reduce the required quality measures by 1 measure for each of the MVPs?
- In addition to testing, what other information or methods should be used to mitigate concerns about administrative claims-based quality measure reliability, applicability, and degree of actionable feedback for clinician performance improvement? What concerns should be prioritized?

(5) Clinician Data Feedback

Clinicians have expressed an interest in leveraging data to track performance and inform care improvements. We see the critical need for data feedback and

[111] The Acute Hospital Utilization and Emergency Department Utilization measures and specifications were developed by the National Committee for Quality Assurance (''NCQA'') under the Performance Measurements contract (HHSM–500–2006–00060C) with CMS and are included in HEDIS® with permission of CMS. HEDIS is a registered trademark of NCQA.

intend to provide enhanced clinician driven data feedback and analysis information under the future MVP approach. We understand that performance data feedback on administrative claims-based quality and cost measures would potentially assist clinicians in understanding their performance and preparing to take on risk as required in Advanced APMs. We are interested in whether clinicians would benefit from receiving feedback on administrative data that is available to us, such as information on the services that their patients receive or information on the clinician's volume of services in comparison to their peers to determine if the clinician is an outlier. Clinicians may also benefit from timely actionable clinical data feedback from registries, and we have proposed to enhance data feedback requirements for QCDRs and registries in sections III.K.3.g.(2)(a)(iii) and III.K.3.g.(3)(a)(ii) respectively of this proposed rule. We also understand the need for timely data feedback and are seeking comments on clinician data feedback content and timing needs.

(a) Request for Feedback on Clinician Data Feedback

We are requesting public comments on the Clinician Feedback.

- We would like to provide meaningful clinician feedback on administrative claims-based quality and cost measures. As clinicians and groups move towards joining APMs, is there particular data from quality and cost measures that would be helpful?
- Would it be useful to clinicians to have feedback based on an analysis of administrative claims data that includes outlier analysis or other types of actionable data feedback? What type of information about practice variation, such as the number of procedures performed compared to other clinicians within the same specialty or clinicians treating the same type of patients, would be most useful? What level of granularity (for example, individual clinician or group performance) would be appropriate?

(6) Enhanced Information for Patients

(a) Patient Reported Measures

We intend to incorporate more patient reported outcomes and care experience measures into MVPs. We want to learn how patient reported information is being effectively used in the field to improve care to assist patients with clinician selection and to incentivize high value care. We believe that feedback from the patient perspective can inform care improvement efforts as clinicians assess patient reported feedback to identify ways to elevate quality of care.

MIPS currently includes patient reported measures, including optimal asthma control and measures for functional status assessment following hip and knee replacements, and other patient reported measures are being added. We recognize current limitations with the availability of patient reported measures. Patient reported measures are often specific to a clinical condition or procedure, and we do not have measures that are available or applicable to the majority of clinicians in the MIPS program. The Consumer Assessments of Healthcare Providers and Systems (CAHPS) for MIPS survey, a patient experience survey, is offered to group practices as an optional quality measure and is a high-weighted improvement activity. Section III.K.3.c.(1)(c)(i) of this proposed rule discusses initiatives to expand the information collected in the CAHPS for MIPS survey.

We have assessed additional approaches to gathering information on experience and satisfaction from work both within and outside of the health care environment. The Robert Wood Johnson Foundation working with Patients Like Me, a health information sharing website for patients, has provided guidance on what should be measured through a publication entitled ''Development of a Conceptual Framework of ''Good Healthcare'' from The Patient's Perspective'' [112] We understand that some organizations such as Patients Like Me are working with patients throughout the measure development process to enhance their ability to capture information that is useful to patients. Outside of healthcare, many industries are approaching the measurement of satisfaction as a business priority. Service industries have pioneered single question ''surveys'' asked at each encounter to learn if they are meeting customer expectations and satisfying their customers, that could include a question about the service provided or whether the assistance provided addressed their problems. We are interested in how information from single question or brief surveys to measure the quality of patient experience and satisfaction with health care delivery could be better incorporated into MVPs.

[112] *https://patientslikeme_posters.s3.amazonaws.com/2017_Development%20of%20a%20Conceptual%20Framework%20of%20%E2%80%9CGood%20Healthcare%E2%80%9D%20from%20The%20Patient%E2%80%99s%20Perspective.pdf.*

(i) Request for Feedback on Patient Reported Measures

We are requesting public comments on enhancing the patient voice in MVPs. Specifically, we seek comment on:

- What patient experience/satisfaction measurement tools or approaches to capturing information would be appropriate for inclusion in MVPs? How could current commercial approaches for measuring the customer experience outside of the health care sector (for example, single measures of satisfaction or experience) be developed and incorporated into MVPs to capture patient experience and satisfaction information?
- What approaches should we take to get reliable performance information for patients using patient reported data, in particular at the individual clinician level? Given the current TIN reporting structure, are there recommendations for ensuring clinician level specific information in MVPs? Should clinicians be incentivized to report patient experience measures at the individual clinician level to facilitate patients making informed decisions when selecting a clinician, and, if so, how?
- How should patient-reported measures be included in MVPs? How can the patient voice be better incorporated into public reporting under the MVP framework, in particular at the individual clinician level?

(b) Publicly Reporting MVP Performance Information

We believe implementing a path to value will transform our healthcare system by empowering well-informed patients to make decisions about their healthcare and helping clinicians achieve better outcomes. As we consider publicly reporting MVP performance information, we want to ensure that patients have information that is important and useful, which we believe includes information on clinician performance on cost, quality, patient experience, and satisfaction with care.

Currently, all MIPS quality measure information is displayed on Physician Compare clinician and group profile pages at the individual quality measure level. User testing with patients and caregivers has shown that performance on certain individual quality measures is particularly useful for selecting clinicians for their healthcare needs. However, testing has also shown that patients and caregivers are interested in a single overall rating called a ''value indicator'' for a clinician or group when making comparisons across groups or clinicians. To date, a ''value indicator'' to compare the performance of a

clinician or group has not been possible due to the current approach in which clinicians can select from an inventory of measures across a variety of collection types and activities. Since clinicians are not all reporting on the same quality measures, we have been unable to develop direct overall comparisons under our public reporting standards. However, we believe that MVPs, in which clinicians of a particular specialty are held accountable for a uniform set of quality and cost measures, would better allow for such comparisons.

Related to the MVP approach, we seek comment on the types of clinician performance information we should include in the display for a single ''value indicator''. As we think about value and information that is important to patients, we want to incorporate measurement of cost, quality, and patient experience and satisfaction in a way that is meaningful to patients. We have heard that Medicare patients and caregivers greatly desire information such as a value indicator, to help make decisions about their healthcare. We seek comment on whether displaying an overall indicator for the MVP for a clinician or group would be useful for patients' making healthcare decisions. We refer readers to the Public Reporting on Physician Compare at section III.K.3.h.(4) of this proposed rule for additional considerations for publicly reporting these types of information such as a value indicator, patient narratives, and patient reported outcome measures.

(i) Request for Feedback on Publicly Reporting MVP Performance Information

We seek feedback on approaches to publicly reporting MVP performance information:

- What considerations should be taken into account if we publicly report a value indicator, as well as corresponding measures and activities included in the MVPs?
- If we develop a value indicator, what data elements should be included? For example, should all reported measures and activities be aggregated into the value indicator?
- How would a value indicator, based on information from MVPs, be useful for patients making health care decisions?
- What methods of displaying MVP performance information should we consider other than our current approach to using star ratings for quality measure information on clinician profile pages?
- What factors should be considered to ensure publicly reported MVP information is comparable across relevant clinicians and groups?

b. Group Reporting

For previous discussions of the policies for group reporting, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77070 through 77073) and the CY 2018 Quality Payment Program final rule (82 FR 53592 through 53593). In addition, for previous discussions of the policies for group reporting related to the Promoting Interoperability performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77214 through 77216) and the CY 2018 Quality Payment Program final rule (82 FR 53687).

It has come to our attention that the regulation text regarding group reporting at § 414.1310(e)(3) through (5) contains duplicative language. Specifically, it is duplicative of the regulation text at § 414.1310(e)(2)(ii) through (iv). To avoid redundancy and potential confusion, we are proposing to remove § 414.1310(e)(3) through (5). In addition, we have noticed that previously established policies for group reporting with regard to the Promoting Interoperability performance category (81 FR 77214 through 77216, 82 FR 53687) are not reflected in the regulation text for group reporting at §§ 414.1310(e)(2)(ii) and for virtual groups at § 414.1315(d)(2). In the CY 2017 Quality Payment Program final rule (81 FR 77215), we stated that to report as a group for the Promoting Interoperability performance category, the group will need to aggregate data for all of the individual MIPS eligible clinicians within the group for whom they have data in CEHRT. In an effort to more clearly and concisely capture our existing policy for the Promoting Interoperability performance category, we are proposing to revise §§ 414.1310(e)(2)(ii) and 414.1315(d)(2. Specifically, we are proposing to revise § 414.1310(e)(2)(ii) to state that individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

Similarly, we are proposing to revise § 414.1315(d)(2) to state that solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

We request comments on these proposals.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to § 414.1330 through § 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In the CY 2020 PFS proposed rule, we seek to:

- Propose to weigh the quality performance category at 40 percent for the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, 30 percent for the 2024 MIPS payment year as described in § 414.1330(b)(4), (5), and (6); The associated increases to the weight of the cost performance category are discussed in section III.K.3.c.(2) of this proposed rule;
- Seek comment on adding narratives to the CAHPS for MIPS survey and on whether the survey should collect data at the individual eligible clinician level;
- Propose to increase the data completeness criteria to 70 percent for the 2022 MIPS payment year as described in § 414.1340(b)(3);
- Propose to require MIPS quality measure stewards to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible;
- Seek comment as to whether we should consider realigning the MIPS quality measure update cycle with that of the eCQM annual update process;
- Propose changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, including: Substantive changes to existing measures, addition of new measures, removal of existing measures, and updates to specialty sets.
- Seek comment on whether we should increase the data completeness threshold for extremely topped out quality measures that are retained in the program due to limited availability of measures for a specific specialty and potential alternative solutions in addressing extremely topped out measures;
- Propose to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in

the program for 2 consecutive CY performance periods;

- Propose to remove quality measures from the program in instances where the measure steward or owner refuses to enter into a user agreement with CMS; and
- Request information on a Potential Opioid Overuse Measure.

(b) Contribution to Final Score

Under § 414.1330(b)(2), we state that performance in the quality performance category will comprise 50 percent of a MIPS eligible clinician's final score for the 2020 MIPS payment year, and under § 414.1330(b)(3), we state that performance in the quality performance category will comprise 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021. Section 1848(q)(5)(E)(i)(I) of the Act, as amended by section 51003(a)(1)(C)(i) of the Bipartisan Budget Act of 2018, provides that 30 percent of the final score shall be based on performance for the quality performance category, but that for each of the 1st through 5th years for which MIPS applies to payments, the quality performance category performance percentage shall be increased so that the total percentage points of the increase equals the total number of percentage points that is based on the cost performance category performance is less than 30 percent for the respective year. As discussed in section III.K.3.c.(2) of this proposed rule, we propose to weight the cost performance category at 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Accordingly, we are proposing to add § 414.1330(b)(4) to provide that performance in the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. In addition, we are proposing at § 414.1330(b)(5) to state that the quality performance category comprises 35 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year. Lastly, we are proposing to add § 414.1330(b)(6) to state that the quality performance category comprises 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and future years. We believe that being transparent in how both the quality and cost performance category weights will be modified over the next few years of the program will allow stakeholders to better plan and anticipate how eligible clinicians and group scores will be calculated in future years as we incrementally make changes to the final score weights. We seek comment on our proposals to incrementally reduce the weight of the quality performance category as we gradually increase the weight of the cost performance category. Specifically, the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and future years.

(c) Quality Data Submission Criteria

(i) Submission Criteria for Groups Electing To Report the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

We are not proposing any changes to the established submission criteria for the CAHPS for MIPS Survey. We refer readers to the CY 2019 PFS final rule (83 FR 59756) for previously finalized policies regarding the CAHPS for MIPS survey.

Although we are not making any proposals in regard to the CAHPS for MIPS survey this year, we are interested in feedback to add to the survey, in future years, specific to a solicitation of comments we previously requested to expand the survey to add narratives in the CY 2018 Quality Payment Program final rule (82 FR 53630). Currently, the CAHPS for MIPS survey is available for only groups to report under the MIPS. The patient experience survey data that is available on Physician Compare is highly valued by patients and their caregivers as they evaluate their health care options. However, in user testing with patients and caregivers over the last several years, the users regularly request more information from patients like them in their own words, and to publicly report narrative reviews of individual clinicians and groups. User testing further indicates that patients want patient-generated information when selecting a clinician. Since the CAHPS for MIPS survey is only at the group level, we are also interested in feedback related to collection of data on patient experiences from individual clinicians, which would be new data for CMS and consequently new data to publicly report to patients and caregivers. Including data at the individual level is of interest to CMS as we have heard this is valuable to patients and caregivers in making decisions related to their health care. See section III.K.3.h. of this proposed rule where we are seeking comment on public reporting considerations on the Physician Compare website for adding patient narratives in future rulemaking.

Through efforts such as the Patients Over Paperwork initiative and MyHealthEData initiative (*https://www.cms.gov/newsroom/press-releases/trump-administration-announces-myhealthedata-initiative-put-patients-center-us-healthcare-system*), we are dedicated to putting patients first and empowering patients to have the information they need to be engaged and active decision-makers in their care. We are also mindful that a patient is a health care consumer for whom aspects of the health care delivery experience, such as wait times or how a clinician interacts with patients, may factor into a patient's decision to select a clinician. We believe that measuring patient experience can help inform patient decision-making and considered previous government efforts to measure experience, such as the President's Management Agenda—OMB Circular No. A–11 section 280—Managing Customer Experience and Improving Service Delivery (*https://www.whitehouse.gov/wp-content/uploads/2018/06/s280.pdf*). Specifically, the OMB Circular No. A–11 section 280.7 references how should customer experience be measured in the federal government. At a minimum, the federal government customer experience should be measured in seven domains: [113]

- *Overall:* (1) Satisfaction; (2) Confidence/Trust.
- *Service:* (3) Quality.
- *Process:* (4) Ease/Simplicity; (5) Efficiency/Speed; (6) Equity/Transparency.
- *People:* (7) Employee Helpfulness.

While the CAHPS for MIPS survey is an assessment of clinicians within a group, we are looking at ways to enhance that feedback to ensure the customer (patient) experience is being measured in such a way that data from the CAHPS for MIPS survey can be used in healthcare decision making. We are seeking comments on the above referenced seven domains and if additional elements, questions, or context should be added to the current CAHPS for MIPS survey (available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/459/2019%20CAHPS%20for%20MIPS%20Survey_Sample%20Copy.pdf*), or if these domains should be used to measure individual clinicians if a new instrument was developed to gather that data and share the feedback with

[113] President's Management Agenda (2018)—OMB Circular No. A–11 section 280—Managing Customer Experience and Improving Service Delivery (*https://www.whitehouse.gov/wp-content/uploads/2018/06/s280.pdf*).

patients to make decisions about their healthcare.

For considerations as we prepare for future policies and rulemaking, we are also seeking comment on:

- Measures that would expand the information collected in the CAHPS for MIPS survey, including a question regarding the patients' overall experience and satisfaction rating with a recent health care encounter. Patients value the ''voice'' of other patients and want information that helps to choose their clinicians, and whether they would recommend the clinician, group, office or facility to their family and friends, as detailed in section III.K.3.a. of this rule. Several versions of the CAHPS survey, including the CAHPS Clinician & Group Survey 3.0, do have a question regarding the patients' rating of a clinician. We refer readers to the Agency for Healthcare Research and Quality's website on CAHPS Clinician and Group Survey for additional information at *https://www.ahrq.gov/cahps/surveys-guidance/cg/index.html*. We currently do not collect and display information from a single question about the patients' satisfaction or experience. Patient experience measures provide a more objective assessment of health care quality, since satisfaction may change frequently based on subjective expectations. The CAHPS for MIPS survey has traditionally focused on measures of patient experience.
- Method for collecting this type of information from patients and caregivers and if a web, paper, phone, or email based survey would be preferred? Currently the CAHPS for MIPS survey is only administered through paper and phone based methods.
- Should a tool be developed to collect information about individual clinicians? Or should this information be kept at the group level only? Currently patient experience data is only available through the CAHPS for MIPS survey, and this survey does not collect information on individual clinicians.
- Should this data be collected at a pilot level first, provided that such an approach is consistent with our statutory authority, so that we learn from this data before fully implementing broader across the program? If so, we seek comments regarding the framework and implementation criteria of a pilot.

In addition, we are seeking comment on the value of using narrative questions, inviting patients to respond to a series of questions in free text responding to open ended questions and describing their experience with care. Patients can write a response in their own words. We would build from work done by AHRQ to develop a Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*), which is a set of open-ended questions that prompt patients to tell a clear and comprehensive story about their experience with a clinician. Narratives from patients about their health care experiences can provide a valuable complement to standardized survey scores, both to help clinicians understand what they can do to improve their care and to engage and inform patients about differences among clinicians. Five questions underwent initial item development for the Clinician & Group CAHPS Survey, focusing on the patient's relationship with the clinician, patient expectations, how the expectations were met, what went well, and what could have been better. We believe patients will be interested in this information to make informed decisions about their healthcare. In section III.K.3.c.(1), we seek comment on how the free text questions might be scored as part of the Quality Payment Program. We seek comment on the value of collecting and displaying information from narrative questions, and whether stakeholders have concerns with the potential burden involved with drafting narrative responses. We also are interested in understanding whether clinicians would find this information useful in improving the care they provide to beneficiaries

As we continue learning about what patient experience data and format is most usable to patients, caregivers, and clinicians we plan to conduct additional item development and testing of implementation processes at CMS. Information gathered from these activities, along with comments received from this rule will be taken into consideration as we consider future policies for future rulemaking, using a human-centered design approach where applicable.

(ii) Data Completeness Criteria

We refer readers to the CY 2019 PFS final rule (83 FR 59756 through 59758) where we discuss and codified at § 414.1340 finalized data completeness criteria.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53632 through 53634), we anticipated on proposing increases to the data completeness thresholds for data submitted on quality measures (QCDR measures, MIPS CQMs, eCQMs, and Medicare Part B Claims measures) in future years of the program. For MIPS payment years 2019 and 2020, the data completeness threshold was finalized and retained at 50 percent. We provided an additional year for individual MIPS eligible clinicians and groups to gain experience with MIPS before increasing the data completeness threshold for MIPS payment year 2021, for which the data completeness threshold was finalized at 60 percent.

We continue to believe it is important to incorporate higher data completeness thresholds over time to ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures. We previously noted concerns raised about the unintended consequences of accelerating the data completeness thresholds too quickly, which may jeopardize a MIPS eligible clinicians' ability to participate and perform well under MIPS. We want to ensure that an appropriate yet achievable data completeness is applied to all eligible clinicians participating in MIPS. Based on our analysis of data completeness rates from data submission for the 2017 performance period of MIPS, as described in Table 35, we believe that it is feasible for eligible clinicians and groups to achieve a higher data completeness threshold.

TABLE 35—CY 2017 DATA COMPLETENESS RATES FOR MIPS INDIVIDUAL ELIGIBLE CLINICIANS, GROUPS, AND SMALL PRACTICES

Average data completeness rate—individual eligible clinician	Average data completeness rate—groups	Average data completeness rate—small practices
76.14	85.27	74.76

With the support of the data in Table 35, we propose to amend § 414.1340 to add paragraph (a)(3) to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMS must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the 2020 MIPS performance period. As we observe increased use of electronic methods of reporting, such as EHRs and QCDRs, we believe it is important to continue to increase the data completeness threshold, and are interested in stakeholder feedback on an appropriate incremental approach, and on how this incremental increase should be implemented. In crafting our proposal, we also considered other thresholds, such as a higher threshold of 80 percent, but have concerns that requiring every clinician or group to adhere to an increased data completeness threshold that is increased by such a large amount may be considered burdensome to clinicians. We are requesting comments on other considerations or possible thresholds we should consider, such as whether we should increase the data completeness threshold to 80 percent to provide for more accurate assessments of quality.

We have received inquiries regarding perceived opportunities to selectively submit MIPS data that are unrepresentative of a clinician or group's performance, suggesting that certain parties may have misunderstood the intent of our incremental approach to the data completeness thresholds, and may not fully appreciate their current regulatory obligations. As stated in §§ 414.1390(b) and 414.1400(a)(5), all MIPS data submitted by or on behalf of a MIPS eligible clinician, group, or virtual group must be certified as true, accurate and complete. MIPS data that are inaccurate, incomplete, unusable, or otherwise compromised can result in improper payment. Using data selection criteria to misrepresent a clinician or group's performance for a performance period, commonly referred to as ''cherry-picking,'' results in data that are not true, accurate, or complete. Accordingly, we propose to further amend § 414.1340 to add a new subsection (d) to clarify that if quality data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5). We believe this clarification will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance.

We continue to strongly urge all MIPS eligible clinicians to report on quality measures where they have performed the quality actions with respect to all applicable patients.

We would like to note that we are not proposing any changes to § 414.1340(c), which states that groups submitting quality measures data using the CMS Web Interface or a CMS-approved survey vendor to submit the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable. We refer readers to the CY 2019 PFS final rule (83 FR 59756 through 59758) for additional discussion of this requirement. Table 36 describes the data completeness requirements by collection type.

TABLE 36—SUMMARY OF DATA COMPLETENESS REQUIREMENTS AND PERFORMANCE PERIOD BY COLLECTION TYPE FOR THE 2020 MIPS PERFORMANCE PERIOD

Collection type	Performance period	Data completeness
Medicare Part B claims measures	Jan 1–Dec 31	70 percent sample of individual MIPS eligible clinician's, or group's Medicare Part B patients for the performance period.
QCDR measures, MIPS CQMs, and eCQMs.	Jan 1–Dec 31	70 percent sample of individual MIPS eligible clinician's, or group's patients across all payers for the performance period.
CMS Web Interface measures	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.
CAHPS for MIPS survey measure	Jan 1–Dec 31	Sampling requirements for the group's Medicare Part B patients.

(d) Selection of MIPS Quality Measures

(i) Call for Measures and Measure Selection Process

In the CY 2019 PFS final rule (83 FR 59758 through 59761), we discuss the importance of classifying measures by meaningful measure areas, and updates to the definition of a high priority measure. We refer readers to the CY 2019 PFS final rule for additional details.

Furthermore, in the CY 2018 Quality Payment Program final rule (82 FR 53635 through 53637), we state that quality measure submissions submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual Call for Measures, which is further described through the CMS Pre-Rulemaking website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.html*. The annual Call for Measures process allows for eligible clinician organizations and other relevant stakeholder organizations to identify and submit quality measures for consideration. Presumably, stakeholders would not submit measures for consideration unless they believe the measures are applicable to clinicians and can be reliably and validly measured. Through the annual convention of the consensus-based entity, stakeholders are given the opportunity provide input on whether or not they believe measures are applicable to clinicians, feasible, scientifically acceptable, reliable, and valid at the clinician level. We intend to continue to submit future MIPS quality measures to the consensus-based entity, as appropriate, and consider the recommendations provided as part of the comprehensive assessment of each measure considered for inclusion in MIPS. In addition, we must go through notice and comment rulemaking to consider stakeholder feedback prior to

finalizing the annual list of quality measures. Furthermore, as required by statute, new measures must be submitted to an applicable specialty-appropriate, peer-reviewed journal. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53636) for additional details on the peer-reviewed journal requirement.

In the CY 2018 Quality Payment Program final rule (82 FR 53636), we requested stakeholders apply the following set of considerations when submitting quality measures for possible inclusion in MIPS:

- Measures that are not duplicative of an existing or proposed measure.
- Measures that are beyond the measure concept phase of development, with a strong preference for measures that have completed reliability, feasibility, and validity testing.
- Measures that are outcomes-based rather than process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnoses and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address of patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.
- Measures that address significant variation in performance and are not considered topped out.
- Measures that are specified as a collection type other than Medicare Part B Claims. We strongly encourage measure stewards to keep this in mind as they develop and submit measures for consideration.

We also encourage stakeholders to consider electronically specifying their quality measures, as eCQMs, in order to encourage clinicians and groups to move towards the utilization of electronic reporting, as we believe electronic reporting will increase timeliness and efficiency of reporting by replacing manual data entry. In addition to the aforementioned considerations, when considering quality measures for possible inclusion in MIPS, we are proposing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process. We recognize there are instances where costs measures are not available for all clinician specialties or that improvement activities may not be associated with a given quality measure. However, we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities. We seek comments on this proposal.

Furthermore, previously finalized MIPS quality measures can be found in the CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures proposed for inclusion in MIPS for the 2020 performance period and future years are found in Table Group A of Appendix 1 of this proposed rule.

In addition to the individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with choosing quality measures that are most relevant to their scope of practice. The following specialty measure sets have been excluded from this proposed rule because we did not propose any changes to these specialty measure sets: Pathology, Electro-Physiology Cardiac Specialist, and Interventional Radiology. Therefore, for the finalized Pathology specialty measure set, we refer readers to the CY 2019 PFS final rule corrections notice (84 FR 566). In addition, we refer readers to the CY 2018 Quality Payment Program final rule for the finalized Electro-Physiology Cardiac Specialist specialty measure set (82 FR 53990) and the finalized Interventional Radiology specialty measure set (82 FR 54098 through 54099). Our proposals for modifications to existing specialty sets and new specialty sets can be found in Table Group B of Appendix 1 of this proposed rule. Specialty sets may include: New measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Please note that the proposed specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 18, 2019,[114] we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for Year 4 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2019 PFS final rule, the 2019 Measures Under Consideration list, and provides recommendations to add or remove the current MIPS quality measures from existing specialty sets, or provides recommendations for the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and those recommendations that we agree with are being proposed within this proposed rule.

In addition, MIPS quality measures with proposed substantive changes can be found in Table Groups D and DD of Appendix 1 of this proposed rule. As discussed in Table DD of this proposed rule, we have determined based on extensive stakeholder feedback that the 2018 CMS Web Interface measure numerator guidance for the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention measure is inconsistent with the intent of the CMS Web Interface version of this measure as modified in the CY 2018 Quality Payment Program final rule (82 FR 54164) and is unduly burdensome on clinicians. Moreover, due to the current guidance, we are unable to rely on historical data to benchmark the measure. Therefore, for the 2018 MIPS performance period and 2020 MIPS payment year, we are excluding the Web Interface version of this measure from MIPS eligible clinicians' quality scores in accordance with § 414.1380(b)(1)(i)(A)(2). Beginning with reporting for the 2019 MIPS performance period and 2021 MIPS payment adjustment, we are proposing in Table DD of this proposed rule to update the CMS Web Interface measure numerator guidance. To the extent that this proposed change constitutes a change to the MIPS scoring or payment methodology for the 2021 MIPS payment adjustment after the start of the 2019 MIPS performance period, we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to modify the measure as proposed in Table DD of this proposed rule because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure, as modified in the CY 2018 QPP final rule, and unduly burdensome on clinicians. If this modification is finalized as proposed, we expect that we would be

[114] Listserv messaging was distributed through the Quality Payment Program listserv on January 18th, 2019, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets for the Quality Performance Category and/or Revisions to the Existing Specialty Measure Sets for the Quality Performance Category for the 2020 Program Year of Merit-based Incentive Payment System (MIPS).''

able to benchmark and score the CMS Web Interface version of this measure for the 2019 MIPS performance period and 2021 MIPS payment adjustment.

As discussed in section III.E.1.b of this proposed rule, changes to the CMS Web Interface measures for MIPS that are proposed and finalized through rulemaking would also be applicable to ACO quality reporting under the Medicare Shared Savings Program. As discussed in Table Group A of Appendix 1 of this proposed rule, we propose to add 1 new measure to the CMS Web Interface in MIPS. Furthermore, as discussed in Table Group C of Appendix 1 of this proposed rule, we are proposing to remove 1 measure from the CMS Web Interface in MIPS. If finalized, groups reporting CMS Web Interface measures for MIPS would be responsible for reporting the finalized measure set, inclusive of any finalized measure removals and/or additions. We refer readers to the Appendix 1 of this proposed rule for additional details on the proposals related to changes in CMS Web Interface measures.

On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive as described above. We note that the current cycle of measure updates to MIPS quality measures is separate from the eCQM annual update process. An overarching timeline of milestones related to eCQMs available at *https://ecqi.healthit.gov/ecqm-annual-timeline*. We seek stakeholder comment as to whether we should consider realigning the measure update cycle with that of the eCQM annual update process. We note if the update cycles were to align, quality measure specifications updates would be gathered earlier in the year, which may pose an issue when considerations need to be given, but not limited to: Updates to clinical guidelines and changes in NQF endorsement status.

In addition, we refer readers to the CY 2019 PFS final rule (83 FR 59759) for additional details on reporting requirements of eCQM measures. Furthermore, in section III.D. of this proposed rule, we propose to generally align the CY 2020 eCQM reporting requirements for the eligible professionals participating in the Medicaid Promoting Interoperability Program with the MIPS eCQM reporting requirements. We refer readers to section III.D. of this proposed rule for additional details and criteria on the Medicaid Promoting Interoperability Program proposals.

(ii) Global and Population-Based Measures

Section 1848(q)(2)(C)(iii) of the Act provides that the Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the quality performance category. We believe the purpose of global and population-based measures is to encourage systemic health care improvement for the populations being served by MIPS eligible clinicians. In addition, as described in the CY 2017 Quality Payment Program final rule (81 FR 77130 through 77136), we believe that all MIPS eligible clinicians, including specialists and subspecialists, have a meaningful responsibility to their communities, which is why we chose to focus on population health and prevention measures for all MIPS eligible clinicians. It is important to note that an individual's health relates directly to population and community health, which is an important consideration for quality measurement in MIPS and in general. Furthermore, we have heard from stakeholders that we should drive quality measurement towards a set of population-based outcome measures to publicly report on quality of care.

In addition, we believe including additional administrative claims based measures in the program will reduce the burden associated with quality reporting. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. For these reasons, in Table Group AA of Appendix 1 of this proposed rule, we are proposing the inclusion of a population health based quality measure (The All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure) beginning with the 2021 MIPS performance period. We are proposing this measure with a delayed implementation until the 2021 performance period of MIPS, to allow for time to work through operational factors of implementing the measure. Factors include allowing for time for the All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure to go through the Measures Under Consideration and Measures Application Partnership (MAP) process that is typically applied for all MIPS quality measures. We refer readers to section III.K.3.a.(4) of this proposed rule for additional information on our interest to include other global and population-based measures in future years of MIPS, which we envision would include the modification of the submission requirements under the quality performance category.

(iii) Topped Out Measures

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53637 through 53640), where we finalized the 4-year timeline to identify topped out measures, after which we may propose to remove the measures through future rulemaking. We also refer readers to the 2019 MIPS Quality Benchmarks' file that is located on the Quality Payment Program resource library (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*) to determine which measure benchmarks are topped out for 2019 and would be subject to the scoring cap if they are also identified as topped out in the 2020 MIPS Quality Benchmarks' file. We note that the final determination of which measure benchmarks are subject to the topped out cap would not be available until the 2020 MIPS Quality Benchmarks' file is released in late 2019.

In the CY 2019 PFS final rule (83 FR 59761 through 59763), we finalized that once a measure has reached extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), we may propose the measure for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped out measure lifecycle. However, we would also consider retaining the measure if there are compelling reasons as to why it should not be removed (for example, if the removal would impact the number of measures available to a specialist type or if the measure addressed an area of importance to the Agency).

As an example, four of the five quality measures within the pathology specialty set have been identified as extremely topped out in the 2019 benchmarking file. However, we believe that it is important to retain these pathology specific measures in the MIPS quality measure set to ensure that pathologists have a sufficient number of quality measures to report. Quality measures identified as extremely topped out are considered to have high, unvarying performance where no meaningful room for improvement can be identified, and are only identified as such through data received during the submission period. We have heard from stakeholders that

some measures tend to appear topped out or extremely topped out due to clinicians' ability to select measures they expect to perform well on, and because of this, the data we receive is not actually representative of how clinicians perform across the country on these metrics. For this reason, we seek comment on whether we should increase the data completeness threshold for quality measures that are identified as extremely topped out, but are retained in the program due to the limited availability of quality measures for a specific specialty. In addition, we seek comment on potential alternative solutions in addressing extremely topped out measures.

We encourage stakeholders to continue their measure development efforts in creating new pathology specific quality measures that can demonstrate a meaningful performance gap, thereby offering opportunities for quality improvement. We also encourage pathologists to consider reporting on pathology specific QCDR measures through a CMS-approved QCDR available for the 2020 performance period. A list of CMS-approved QCDRs for the 2020 performance period will be made available on or prior to January 1, 2020, and will be posted on the Quality Payment Program resource library at *https://qpp.cms.gov/about/resource-library*.

In addition, in the CY 2019 PFS final rule (83 FR 59761 through 59763), we also finalized our policy to exclude QCDR measures from the topped out measure timeline. When a QCDR measure reaches topped out status, as determined during the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

(iv) Removal of Quality Measures

In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we discussed removal criteria for quality measures, including that a quality measure may be considered for removal if the Secretary determines that the measure is no longer meaningful, such as measures that are topped out. Furthermore, if a measure steward is no longer able to maintain the quality measure, it would also be considered for removal. In addition, in the CY 2019 PFS final rule (83 FR 59763 through 59765), we communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set, we believe incrementally removing non-high priority process measures through notice and comment rulemaking is appropriate. We refer readers to the CY 2019 PFS final rule (83 FR 59763 through 59765) for details on the previously established criteria to remove measures.

In addition to previously established measure removal criteria, we have observed instances where MIPS quality measures have had low reporting rates year over year, and have made it difficult for some MIPS quality measures to achieve a benchmark. As a result, these measures have resulted in clinicians receiving no more than 3 points for each measure that is unable to meet benchmarking criteria. For these reasons, we are proposing to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. We believe that a time period of 2 consecutive CY performance periods is appropriate, as we anticipate that any newly finalized measure would need more than 1 CY performance period in order to observe measure reporting trends, and believe that 2 consecutive CY performance periods allows for sufficient time to monitor reporting volumes. We will factor in other considerations (such as, but not limited to: The robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome) prior to determining whether to remove the measure. Removing measures with this methodology ensures that the MIPS quality measures available in the program are truly meaningful and measureable areas, where quality improvement is sought and that measures that are low reported for 2 consecutive CY performance periods are removed from the program. We believe low reported measures can point to that the measure concept does not provide meaningful measurement to most clinicians. If the measure has too few reporting clinicians and does not meet the case minimum and reporting volumes, but other considerations favor retaining the measure, we may consider keeping the MIPS quality measure, with the caveat that the measure steward should have a plan in place (prior to approval of the measure) to encourage reporting of the measure, such as education and communication or potentially measure specification changes. We seek comments on this proposal. In addition, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for removal. We have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. We believe our proposal to remove the quality measures outlined in Table Group C will lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria.

We have heard from stakeholders concerns on removing measures and the need for more notice before a measure is removed. Therefore, we are interested in what factors should be considered in delaying the removal of measures. For example, we have not heard concerns from stakeholders that selection bias may be impacting low reporting rates, we are interested if this is something we should consider, and how we could determine when low-reporting is due to selection bias versus instances where the measure is not a meaningful metric to the majority of clinicians who would have reported on the measure otherwise. We seek comment on whether we should delay the removal of a specific quality measure by a year, for any of the MIPS quality measures identified for removal. We also request feedback on which quality measure's removal should be delayed for a year, and why.

Furthermore, when we finalize measures to be a part of the MIPS quality measure inventory for a given MIPS payment year, we generally intend that the measures will be available for reporting by or on behalf of all MIPS eligible clinicians since MIPS is a government quality reporting program. It has come to our attention that certain MIPS measure stewards have limited or prohibited the use of their measures by third party intermediaries such as QCDRs and qualified registries. To the extent that MIPS measure stewards limit the availability of previously finalized measures for MIPS quality reporting, including reporting by third party intermediaries on behalf of MIPS eligible clinicians, these limitations may lead to inadvertent increases in burden both for the MIPS eligible clinicians who rely on third party intermediaries and for third party intermediaries themselves. In addition, these limitations may adversely affect our ability to benchmark the measure or the robustness of the benchmark. For these reasons, we propose to adopt an additional removal criterion, specifically, that we may consider a MIPS quality measure for removal if we determine it is not available for MIPS quality reporting by or on behalf of all

MIPS eligible clinicians. We seek comments on this proposal.

(v) Request for Information on Potential Opioid Overuse Measure

To address concerns associated with long-term, high-dose opioids, we developed an electronic clinical quality measure (eCQM) titled: Potential Opioid Overuse. The Potential Opioid Overuse measure captures the proportion of patients aged 18 years or older who receive opioid therapy for 90 days or more with no more than a 7-day gap between prescriptions with a daily dosage of 90 morphine milligram equivalents (MME) or higher. It is intended to report the extent of long-term, high-dose opioid prescribing with the goal of improving patient safety by reducing the potential for opioid-related harms and encouraging the use of alternative pain management. The measure was field tested in 2017. The testing population included 3 test sites, consisting of 19 practices representing 87 clinicians, for CY 2016. Initial results from measure testing indicated that this measure is important, feasible, reliable, valid, and usable. Stakeholders supported the measure concept's importance in addressing a quality improvement opportunity in a priority population.

Through interviews primarily with EHR vendors, we have identified potential challenges for implementing the Potential Opioid Overuse measure. The human readable CQL-based specification is more than 200 pages long in order to accommodate a library providing more information on opioid medications than is currently available to export for the Value Set Authority Center (VSAC). Vendors expressed concerns about the feasibility of accurately capturing some of the medication-specific data elements within the measure, such as medication start and end dates and times, because these are not consistently captured during typical workflows.

We seek to mitigate the usability and feasibility issues for the measure by gathering information from a wider audience of technical implementers to strengthen the potential for measure adoption. We invite public comment on the Potential Opioid Overuse CQL-based specifications in this section. Specifically, we seek comment on the following questions:

- Would you select this measure to support your quality measure initiatives? Why?
- Would you implement this measure in its current state? Why?
- How can we improve the usability of this measure?
- This measure performs medication calculations, to calculate MME, which helps compare different opioids and opioid dosages. Are there any workflow, mapping, or other implementation factors to consider related to the required medication related data elements needed to perform the MME calculations in this measure? Specifically related to: Use of the opioid data library, which clearly lists the required medication information directly in the measure specification; Use of medication end dates, to calculate medication durations; Use of coded medication frequencies, such as ''3 times daily'' or ''every 6 hours,'' required to calculate daily medication dosages.
- Are there any other foreseeable challenges to implementing this measure?

(2) Cost Performance Category

For a description of the statutory basis and our existing policies for the cost performance category, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule (81 FR 77162 through 77177, 82 FR 53641 through 53648, and 83 FR 59765 through 59776, respectively).

In this year's rule, we are proposing to:

- Weight the cost performance category at 20 percent for MIPS payment year 2022, 25 percent for MIPS payment year 2023, and 30 percent for MIPS payment year 2024 and all subsequent MIPS payment years;
- Change our approach to proposing attribution methodologies for cost measures by including the methodology in the measure specifications;
- Add 10 episode-based measures;
- Modify the total per capita cost and Medicare Spending Per Beneficiary (MSPB) measures; and
- Seek comments on the future inclusion of an additional episode-based measure.

These proposals are discussed in more detail in the following sections of this proposed rule.

(a) Weight in the Final Score

In the CY 2019 PFS final rule, we established at § 414.1350(d)(3) that the weight of the cost performance category is 15 percent of the final score for the 2021 MIPS payment year (83 FR 59765 through 59766). Section 51003(a)(1)(C) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA of 2018) amended section 1848(q)(5)(E)(i)(II)(bb) of the Act such that for each of the second, third, fourth, and fifth years for which the MIPS applies to payments, not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category score. Additionally, section 1848(q)(5)(E)(i)(II)(bb) of the Act as amended states that it shall not be construed as preventing the Secretary from adopting a 30 percent weight if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period.

In the CY 2019 PFS proposed rule, we solicited comments on how we should weight the cost performance category for the 2022 and 2023 MIPS payment years given the changes within the BBA of 2018 (83 FR 35901). Several commenters noted that the increased flexibility provided by the BBA of 2018 should be used to maintain the weight at 10 percent for MIPS payment year 2021 and in future years. A few commenters were concerned about increasing the weight of the cost performance category because of the challenges with the existing attribution and risk-adjustment methodologies. Some commenters recommended that the cost performance category weight should be increased to 30 percent as soon as possible. We considered these comments when we developed our proposals for setting the weight of the cost performance category in this proposed rule.

We are proposing a steady increase in the weight of the cost performance category from the existing weight of 15 percent for the 2021 MIPS payment year to 30 percent beginning with the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. We believe this gradual and predictable increase would allow clinicians to adequately prepare for the 30 percent weight while gaining experience with the new cost measures. We recognize that cost measures are still being developed and that clinicians may not have the same level of familiarity or understanding of cost measures that they do of comparable quality measures. We also recognize that there may be greater understanding of the measures in the cost performance category as clinicians gain more experience with them.

We are proposing at § 414.1350(d)(4) that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year. We plan to increase the weight of the cost performance category at standard increments of 5 percent each year until

MIPS payment year 2024. Therefore, we propose at § 414.1350(d)(5) to weight the cost performance category at 25 percent for the 2023 MIPS payment year and propose at § 414.1350(d)(6) to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. This would allow us to meet the 30 percent cost performance category weight when required by the statute and give clinicians adequate time to gain experience with the cost measures while they represent a smaller portion of the final score. We also believe that a predictable increase in the weight of the cost performance category each year would allow clinicians to better prepare for each year going forward. We considered maintaining the weight of the cost performance category at 15 percent for the 2022 and 2023 MIPS payment years as we recognize that we are still introducing new measures for the cost performance category and clinicians are still gaining familiarity and experience with these new measures. However, recognizing that we are required by the statute to weight the cost performance category at 30 percent beginning with the 2024 MIPS payment year, we are concerned about having to increase the cost performance category's weight significantly for the 2024 MIPS payment year. We invite comments on whether we should consider an alternative weight for the 2022 and/or 2023 MIPS payment years.

In accordance with section 1848(q)(5)(E)(i)(II)(bb) of the Act, we will continue to evaluate whether sufficient cost measures are included under the cost performance category as we move towards the required 30 percent weight in the final score. As described in section III.K.3.c.(2)(b)(iii) of this proposed rule, we are proposing to add 10 episode-based measures to the cost performance category beginning with the 2020 MIPS performance period. We are continuing our efforts to develop more robust and clinician-focused cost measures. We will also be continuing to work on developing additional episode-based measures that we may consider proposing for the cost performance category in future years to address additional clinical conditions. Introducing more measures over time would allow more clinicians to be measured in this performance category, with an increasing focus on costs associated with services provided by clinicians for specific episodes of care. In section III.K.3.c.(2)(b)(v) of this proposed rule, in efforts to ensure that our existing cost measures hold clinicians appropriately accountable, we propose modifications to both the total per capita cost and MSPB measures.

(b) Cost Criteria

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. We will continue to evaluate cost measures that are included in MIPS on an ongoing basis and anticipate that measures could be added, modified, or removed through rulemaking as measure development continues. Any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking, following review by the Measure Applications Partnership (MAP). We would take all comments and feedback from both the public comment period and the MAP review process into consideration as part of the ongoing measure evaluation process. For the CY 2020 performance period and future performance periods, we propose to add 10 newly developed episode-based measures to the cost performance category in section III.K.3.c.(2)(b)(iii) of the proposed rule and propose modifications to both the total per capita cost and MSPB measures in section III.K.3.c.(2)(b)(v) of this proposed rule. In section III.K.3.c.(2)(b)(viii) of this proposed rule, we summarize all new and existing measures that would be included in the cost performance category starting with the CY 2020 performance period. Some modifications to measures used in the cost performance category may incorporate changes that would not substantively change the measure. Examples of such non-substantive changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. However, as described in section 3 of the Blueprint for the CMS Measures Management System Version 14.1 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), if substantive changes to these measures that are owned and developed by CMS become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the MAP. The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are applicable to clinicians and complement program-specific statutory and regulatory requirements. Through its Measure Selection Criteria, the MAP focuses on selecting high-quality measures that address the NQF's three aims of better care, healthy people/communities, and affordable care, as well as fill critical measure gaps and increase alignment among programs.

In section III.K.3.c.(2)(b)(v)(A) of this proposed rule, we have summarized the timeline for measure development, including stakeholder engagement activities that are undertaken by the measure development contractor, which include a technical expert panel (TEP), clinical subcommittees, field testing, and education and outreach activities.

(ii) Attribution

In this section of the proposed rule, we discuss our approach to the attribution methodology for cost measures along with revisions to our existing cost measures. In the CY 2017 Quality Payment Program final rule (81 FR 77168 through 77169), we adopted an attribution methodology for the total per capita cost measure under which beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries used in the Shared Savings Program. We codified this policy under § 414.1350(b)(2) in the CY 2019 PFS final rule (83 FR 59774). In the CY 2017 Quality Payment Program final rule (81 FR 77174 through 77176), we also adopted an attribution methodology for the MSPB measure under which an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period. We codified this policy under § 414.1350(b)(3) in the CY 2019 PFS final rule (83 FR 59775).

In the CY 2019 PFS final rule (83 FR 59775), we established at § 414.1350(b)(6) that for acute inpatient medical condition episode-based measures, an episode is attributed to each MIPS eligible clinician who bills inpatient E/M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E/M claim lines in that

hospitalization, and at § 414.1350(b)(7) that for procedural episode-based measures, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

As discussed in section III.K.3.c.(2)(b)(v) of this proposed rule, we have reevaluated the total per capita cost and MSPB measures. In the process of evaluating these measures, the TEP identified areas for potential refinement within the attribution methodology, and the revised measures that we propose include substantial changes to the attribution methodology. As we explain in section III.K.3.c.(2)(b)(v), we believe these new attribution methodologies better establish the relationship between the clinician and the patients. In general, for the cost performance category, we believe that attribution is a fundamental element of the measures, and we do not believe that a cost measure can be separated from its attribution methodology. Although in prior rulemaking, we have discussed the attribution methodologies for the cost performance category measures in the preamble and included those methodologies in the regulation text, we intend to take a different approach going forward and address attribution as part of the measure logic and specifications. For this proposed rule and in future rulemaking, we will include the attribution methodology for each cost performance category measure in the measure specifications, which are available for review and public comment at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html* during the public comment period for the proposed rule, and will be available in final form at *https://qpp.cms.gov/about/resource-library* after the final rule is published. We believe this approach is preferable because it would reduce complexity for MIPS eligible clinicians and other stakeholders by presenting the attribution methodology with the rest of the cost measure specifications, ensure non-substantive changes could be implemented without undertaking rulemaking, and align with the approach taken for measures in the quality performance category. Therefore, we propose to revise § 414.1350(b)(2), (3), (6), and (7) to reflect that these previously finalized attribution methods apply for the 2017 through 2019 performance periods. We also propose to establish at § 414.1350(b)(8) that beginning with the 2020 performance period, each cost measure would be attributed according to the measure specifications for the applicable performance period.

In the CY 2017 Quality Payment Program final rule, we established a final policy to attribute cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual (the TIN/NPI level) or as part of a group (the TIN level) (81 FR 77175 through 77176). We codified this policy under § 414.1350(b)(1) in the CY 2019 PFS final rule (83 FR 59774 through 59775). Similar to the attribution methodology for cost measures, we also believe that the level of attribution (TIN/NPI or TIN) is best addressed as part of the measure specifications, allowing for different considerations for group and individual attribution based on the underlying measure specification. For this proposed rule and in future rulemaking, we will include the level of attribution for each cost performance category measure in the measure specifications, which will be publicly available as described in the preceding paragraph. The measure specification documents will provide the methodology for assigning attribution to an individual clinician or a group, which will align with whether the participant is reporting data as an individual clinician or a group under the MIPS program. Therefore, we propose to revise § 414.1350(b)(1) to reflect that the current policy of attributing cost measures at the TIN/NPI level, regardless of whether a clinician's performance for purposes of MIPS is assessed as an individual or a group, applies for the 2017 through 2019 performance periods. We intend for the new regulation text proposed at § 414.1350(b)(8) also to include the level of attribution (individual clinician or group), so we are not proposing additional regulation text. We note that in section III.K.3.c.(2)(b)(vi)(B) of this proposed rule, we propose to limit the assessment of certain cost measures to MIPS eligible clinicians who report as a group based on our assessment of the reliability of the measure at the group and individual level. Although this is not directly related to attribution, it does limit the assessment of certain measures for MIPS eligible clinicians who report as individuals.

(iii) Episode-Based Measures for the 2020 and Future Performance Periods

In this section of the proposed rule, we discuss our proposal to add 10 newly developed episode-based measures to the cost performance category beginning with the 2020 performance period. We developed episode-based measures to represent the cost to Medicare and beneficiaries for the items and services furnished during an episode of care (''episode''). Episode-based measures are developed to compare clinicians on the basis of the cost of the care clinically related to their initial treatment of a patient and provided during the episode's timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which include both Medicare payments and beneficiary deductible and coinsurance amounts. We refer our readers to the CY 2019 PFS final rule for more detail on episode-based measures and how they are established (83 FR 59767).

Prior to presenting our cost measures to the MAP for consideration, the measure development contractor has continued to seek extensive stakeholder feedback on the development of episode-based measures, building on the processes outlined in the CY 2018 PFS final rule (82 FR 53644). These processes included convening a TEP and clinical subcommittees to solicit expert and clinical input for measure development, conducting national field testing on the episode-based measures developed, and seeking input from clinicians and stakeholders through engagement activities.

To gather input on the 10 episode-based measures that we are proposing, the measure development contractor convened 10 clinical subcommittees composed of more than 260 clinicians affiliated with 120 specialty societies through an open call for nominations between February 6, 2018 and March 20, 2018. Applicants who submitted materials after the March 20, 2018 deadline were added to a standing pool of nominees and considered for membership in the measure-specific workgroups. The clinical subcommittees met during an in-person meeting in April 2018 to select episode group(s) for development and provide input on the composition of measure-specific workgroups. The smaller measure-specific workgroups were introduced as a refinement to the measure development process based on feedback from members of the first set of clinical subcommittees. The small group size was intended to facilitate more focused discussions. The workgroups—one for each measure—met through in-person meetings and webinars between June and December 2018 to provide detailed clinical input on each component of the episode-based measures. These components include episode triggers and windows (to limit the timing of services included in the episode), item and service assignment, exclusions,

attribution, and risk adjustment variables.

In addition, the 10 episode-based measures we are proposing were developed with input from the Person and Family Committee, a body of patients and their family members and caregivers who provide input iteratively during the measure development process. Discussions regarding patient and caregiver perspectives on the types of episodes that should be prioritized informed the clinical subcommittees' considerations for episode selection. Throughout measure development, the workgroups engaged in bidirectional conversations with the Person and Family Committee to inform measure specifications. For example, patient perspectives on services perceived as aiding recovery or helping to avoid unnecessary costs and complications helped the workgroup provide recommendations for service assignment, and in turn, the workgroup provided questions to the Person and Family Committee, which helped guide their in-depth interviews. After considering each round of input, clinicians had multiple opportunities to solicit additional information and feedback from Person and Family Committee members. In total, the measure developer conducted 84 interviews with 65–70 Person and Family Committee members via one-on-one interviews during development of the 10 episode-based measures.

Finally, as with the measures finalized in the CY 2019 PFS final rule (83 FR 59767), the 10 episode-based measures we are proposing underwent a measure development process based on high level guidance provided to the measure development contractor by a standing TEP. This TEP provided oversight and cross-cutting guidance to the measure development contractor for development of episode-based measures through four meetings between August 2016 and August 2017.

Further detail can be found in the Measure Development Process document at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf*, which includes a discussion of the detailed clinical input obtained at each step, and details about the components of episode-based measures.

We provided an initial opportunity for clinicians to review their performance under the new episode-based measures via national field testing conducted in fall of 2018. During field testing, we sought feedback from stakeholders on the draft measure specifications, feedback report format, and supplemental documentation through an online form, and we received 67 responses, including 25 comment letters. The measure development contractor shared the feedback on the draft measure specifications with the measure-specific workgroups, who considered it in providing input on further refinements after the end of field testing. A field testing feedback summary report, which details post-field testing refinements added based on the input from the measure-workgroups, is publicly available on the MACRA feedback page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*).

Similar to previous years, we continued to engage clinicians and stakeholders, conducting extensive outreach activities. These activities included general informational email blasts, targeted email outreach to specialty societies, hosting office hours to gather input on additional opportunities for participation and outreach, and hosting the MACRA Cost Measures Field Testing Webinar to provide information about the measure development process and field test reports and a forum for stakeholder questions to ask questions.

Following the successful field testing and review through the MAP process, we propose to add the 10 episode-based measures listed in Table 37 as cost measures for the 2020 performance period and future performance periods.

The detailed specifications for these 10 episode-based measures are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip*. These specifications documents consist of (i) methodology for constructing each measure, and (ii) measure codes list file with medical codes and clinical logic. First, the methodology document provides an overview of the measure, including a description of the measure numerator and denominator, the patient cohort, and the care settings in which the measure is assessed. In addition, the document includes two one-page, high-level overviews of (i) methodology and (ii) clinical logic and service codes, which were added in response to stakeholder feedback regarding provision of documentation with varying levels of detail to ensure the information is accessible to all stakeholders. The methodology document provides detailed descriptions of each logic step involved in constructing the episode groups and calculating the cost measure. Second, the measure codes list file contains the service codes and clinical logic used in the methodology, including the episode triggers, exclusions, episode sub-groups, assigned items and services, and risk adjustors. More information about the attribution methodology for each measure is available in section A.2 of the methodology documentation. In addition, measure justification forms containing testing results for these measures are available at the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*.

TABLE 37—EPISODE-BASED MEASURES PROPOSED FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS

Measure topic	Episode measure type
Acute Kidney Injury Requiring New Inpatient Dialysis	Procedural
Elective Primary Hip Arthroplasty	Procedural.
Femoral or Inguinal Hernia Repair	Procedural.
Hemodialysis Access Creation	Procedural.
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	Acute inpatient medical condition.
Lower Gastrointestinal Hemorrhage *	Acute inpatient medical condition.
Lumbar Spine Fusion for Degenerative Disease, 1–3 Levels	Procedural.
Lumpectomy Partial Mastectomy, Simple Mastectomy	Procedural.
Non-Emergent Coronary Artery Bypass Graft (CABG)	Procedural.

TABLE 37—EPISODE-BASED MEASURES PROPOSED FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS—Continued

Measure topic	Episode measure type
Renal or Ureteral Stone Surgical Treatment	Procedural.

*This measure is being proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of the proposed rule.

(iv) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other stakeholders.

In December 2016, we published the Episode-Based Measure Development for the Quality Payment Program (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-list-of-episode-groups-and-trigger-codes-December-2016.zip*) and requested input on a draft list of care episode and patient condition groups and codes as required by sections 1848(r)(2)(E) and (F) of the Act. We additionally requested feedback on our overall approach to cost measure development, including several pages of specific questions on the proposed approach for clinicians and stakeholders to provide feedback. We used this feedback to modify our cost measure development and ensure that our approach is continually informed by stakeholder feedback. As required by section 1848(r)(2)(G) of the Act, in January 2018, we posted an operational list of 8 care episode groups and patient condition groups that we refined with extensive stakeholder input, along with the codes and logic used to define these episode groups. This operational list is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-Operational-List-of-Care-Episode-and-Patient-Condition-Codes.zip*.

Under section 1848(r)(5)(A)(iii) of the Act, to evaluate the resources used to treat patients with respect to care episode and patient condition groups, the Secretary shall, as the Secretary determines appropriate, conduct an analysis of resources use with respect to care episode and patient condition groups. In accordance with this section, we used the 8 care episode groups and patient condition groups included in the operational list as the basis for the eight episode-based measures that we developed in 2017 through early 2018 and finalized for use in MIPS in the CY 2019 PFS final rule (83 FR 59767–59773). We did not revise this operational list through rulemaking in 2018 as we did not receive stakeholder feedback requesting updates to how these episode groups are defined and there were no new developments requiring revisions. Under section 1848(r)(2)(H) of the Act,we propose to revise the operational list beginning with CY 2020 to include 10 new care episode and patient condition groups, based on input from clinician specialty societies and other stakeholders. The 10 care episode and patient condition groups were included in the draft list that we posted in December 2016 and refined based on extensive stakeholder input as described in section III.K.3.c.(2)(b)(v)(A) of this proposed rule. Our proposed revisions to the operational list beginning with CY 2020 are available on our MACRA feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*. These care episode and patient condition groups serve as the basis for the 10 new episode-based measures that we are proposing in section III.K.3.c.(2)(b)(iii) of this proposed rule for the cost performance category.

(v) Revised Cost Measures

(A) Re-Evaluation Process for the Total per Capita Cost and Medicare Spending per Beneficiary Clinician Measures

For the purpose of assessing performance of MIPS eligible clinicians in the cost performance category, we finalized both the total per capita cost and MSPB measures to be included in the MIPS program in CY 2017 Quality Payment Program final rule (81 FR 77166). We are proposing to modify both of these measures based on stakeholder input from prior public comment periods and recommendations from the TEP. We also propose to modify the measure title from Medicare Spending Per Beneficiary (MSPB) to Medicare Spending Per Beneficiary clinician (MSPB clinician) to distinguish it from measures with similar names in use in other CMS programs and to improve clarity. We propose to change the name from MSPB to MSPB clinician at §§ 414.1350(b)(3) and 414.1350(c)(2).

The measure development contractor convened the TEP for two in-person meetings in August 2017 and May 2018 to provide input on potential refinements to both measures and for a webinar in November 2018 to determine additional refinements to the measures based on feedback received from field testing. The TEP's discussion from the May 2018 meeting can be found in the TEP Summary Report at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panels.html#a0913*. In addition, the measure development contractor convened the MSPB Service Refinement Workgroup, an expert workgroup that the TEP recommended to provide detailed clinical input on service assignment rules for the revised MSPB clinician measure. The MSPB Service Refinement Workgroup convened twice during summer 2018 to develop the service exclusion list. The service exclusion list contains the service codes and logic for services that are

considered clinically unrelated to the index admission of the revised MSPB clinician episodes and are removed from the episodes and measure calculation. The revised measures underwent field testing in fall of October 2018 during which we sought feedback on the refined measure specifications and supplemental documentation through an online form. At the end of field testing, the measure development contractor shared feedback with the standing TEP, which considered the feedback in determining further measure refinements for the total per capita cost measure. The TEP also discussed the MSPB clinician measure after field testing and had the opportunity to provide input on further refinements to this measure. A field-testing feedback summary report is publicly available on the MACRA feedback page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*).

(B) Total per Capita Cost Measure

We finalized the total per capita cost measure for use in MIPS as an important measurement of clinician cost performance. Having been used in the Physician Value Modifier program, it had been tested and was reliable for Medicare populations and was familiar to the clinician community. When we finalized this measure for use in MIPS, we noted that as with all the cost measures, we would maintain this measure and update its specifications as appropriate (82 FR 53643). We continue to believe that the existing measure is appropriate to use in MIPS and continue to be committed to maintaining the cost measures with consideration of stakeholder input and testing. However, as a part of our routine measure maintenance, we re-evaluated the total per capita cost measure. The re-evaluation was informed by feedback received on this measure through prior public comment periods, as described in the CY 2017 (81 FR 77017 through 77018) and CY 2018 (82 FR 53577 through 53578) Quality Payment Program final rules, as well as feedback that arose in the measure development contractor's discussions with the TEP during the process of re-evaluation. This feedback is summarized below:

- The total per capita cost measure's attribution methodology assigned costs to clinicians over which the clinician has no influence, such as costs occurring before the start of the clinician-patient relationship.
- The attribution methodology did not effectively identify primary care relationships between a patient and a clinician and could potentially attribute beneficiaries to a clinician not responsible for the beneficiaries' primary care.
- The measure did not account for the shared accountability of clinicians and that attributing costs to a single clinician or clinician group could cause fragmentation of care.
- The beneficiary risk factors were determined one year prior to the start of the performance period, which would preclude the risk adjustment methodology from reflecting the more expensive treatment resulting from comorbidities and/or complications that might arise during the performance period.
- The feedback summarized above informed the four modifications that we are proposing for the total per capita cost measure.

First, we are proposing to change the attribution methodology to more accurately identify a beneficiary's primary care relationships. This is done by identifying a combination of services that occur within a short period of time and indicate the beginning of a relationship. More specifically, a primary care relationship is identified by a candidate event, defined as the occurrence of an E/M service such as an established patient assisted living visit or an outpatient visit (that is, the E/M primary care service), paired with one or more additional services indicative of general primary care (for example, routine chest X-ray, electrocardiogram, or a second E/M service provided at a later date). The candidate event initiates a year-long risk window from the E/M primary care service. The risk window is the period during which a clinician or clinician group could reasonably be held responsible for the beneficiary's treatment costs, and the initiation of the risk window at the onset of the candidate event ensures that costs are attributed only after the start of the clinician-patient relationship. Only the portion of the risk window that overlaps with the performance period, which is divided into 13 four-week blocks called beneficiary-months, is attributable to a clinician for a given performance period. For example, if the risk window were initiated during one MIPS performance period and ends in the following MIPS performance period, only the beneficiary-months that occur during the earlier MIPS performance period would be attributed to the clinician/clinician group to calculate the measure for that particular MIPS performance period. Dividing the performance period into beneficiary-months allows costs to be assigned to clinicians and clinician groups during the parts of the year they are primarily responsible for the patient's care management.

With this methodology, it is possible for multiple candidate events to occur between a clinician and beneficiary over time, and an additional candidate event occurring during an existing risk window reaffirms and extends the period of the clinician's responsibility. For example, if 2 candidate events for the same clinician and the same beneficiary occur 6 months apart, a separate 12-month risk window initiates from the start of each of these candidate events, and the clinician may be attributed beneficiary-months spanning 18 months and 2 different performance periods. As we described above, for risk windows that span multiple performance periods, only the beneficiary-months contained within a given performance period are used to calculate the measure for that performance period. Beneficiary-months that overlap between the 2 risk windows are collapsed to ensure that costs are only accounted for once. Furthermore, if different clinician groups initiated these 2 risk windows for the same beneficiary, the risk windows would occur concurrently and would be attributed to their respective TINs. Within an attributed TIN, only the clinician with the TIN/NPI combination performing the highest number of candidate events is attributed the beneficiary-months, since this TIN/NPI combination is deemed to have the most substantive relationship with the beneficiary. Finally, multiple TINs and TIN/NPIs billing under different TINs may be attributed beneficiary-months for the same beneficiary during the performance period. This attribution method allows multiple clinicians to be considered for the provision of ongoing primary care for a patient, which accounts for changes in primary care relationships (for example, for beneficiaries who move during the year) and reflects shared clinical responsibility for a patient's care.

To illustrate how candidate events identify primary care relationships, we are providing an example of a clinical scenario in which physicians in the primary care medical practice see a beneficiary as part of the beneficiary's routine health maintenance. A beneficiary is feeling unwell and goes to a medical practice. At the practice, the beneficiary sees a family practice clinician who provides an E/M service (one that has been identified as related to primary care) for routine health maintenance. The clinician prescribes a course of medication as part of the care

plan. The beneficiary returns to the same practice 2 months later when she notices new symptoms. At this visit, she sees a different family practice clinician who examines her, adjusts her care plan, and asks her to return in 3 months for a follow-up in case diagnostic testing or a change in medication is required. These two E/M services that occur within proximity (that is, the initial E/M service and the paired event 2 months later—a second E/M service) constitute the candidate event and indicate that a primary care relationship has begun from the time of the first visit to the medical practice. The first E/M service (identified as related to primary care) opens a one-year period (or risk window) from the date of the service. This is illustrated graphically in section 2.0 of the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-TPCC-measure-specs.zip*. During the risk window, the attributed clinician/clinician group can be held responsible for the overall costs of care for that beneficiary. The TIN for the medical practice would be attributed the beneficiary and the TIN/NPI within this practice that provides the most primary care E/M services that initiate candidate events would be attributed the beneficiary. Under the current total per capita cost measure, the TIN and TIN/NPI would have been attributed this beneficiary from the beginning of the calendar year and held accountable for services the beneficiary might have received before her first visit to the medical practice.

Second, we are proposing to change the attribution methodology to more accurately identify clinicians who provide primary care services, by the addition of service category exclusions and specialty exclusions. Specifically, candidate events are excluded if they are performed by clinicians who (i) frequently perform non-primary care services (for example, global surgery, chemotherapy, anesthesia, radiation therapy) or (ii) are in specialties unlikely to be responsible for providing primary care to a beneficiary (for example, podiatry, dermatology, optometry, ophthalmology). As a result of these exclusions, clinician specialties considered for attribution are only those primarily responsible for providing primary care, such as primary care specialties and internal medicine subspecialties that frequently manage patients with chronic conditions that are in their area(s) of expertise. We do not propose to change the adjustment for specialty; as such, the measure would continue to adjust for specialty to account for variation in cost across clinician specialties and in clinician groups with diverse specialty compositions.

Third, we are proposing to change the risk adjustment methodology to determine a beneficiary's risk score for each beneficiary-month using diagnostic data from the year prior to that month rather than calculating one risk score for the entire performance period using diagnostic data from the previous year. This methodology would better account for any changes in the health status of the beneficiary for the duration of a primary care relationship and during the performance period. In addition, we are proposing to add an institutional risk model to improve risk adjustment for clinicians treating institutionalized beneficiaries.

Fourth, we are proposing to change the measure to evaluate beneficiaries' costs on a monthly basis rather than an annual basis. Specifically, the performance period during which costs are assessed is divided into 13 beneficiary-months, mentioned earlier, allowing for the measure and the risk adjustment model to reflect changes in patient health characteristics at any point throughout the performance period. In addition, this refinement would avoid measuring annualized costs for beneficiaries whose death date occurs during the performance period, which could potentially disincentivize care for older and sicker patients.

Further detail about these proposed changes to the measure, as well as a comparison to the total per capita cost measure as currently specified, is available in the measure specifications documents available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-TPCC-measure-specs.zip*.

The revised total per capita cost measure underwent MAP review during the 2018–2019 cycle. In December 2018, the MAP Clinician Workgroup gave the preliminary recommendation of 'conditional support for rulemaking,' with the condition of NQF endorsement. In January 2019, the MAP Coordinating Committee reversed the Clinician Workgroup's preliminary recommendation and provided a final recommendation of ''do not support for rulemaking with potential for mitigation''. More detail on the mitigating factors is available in the MAP's final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx*. We believe that the revised measure provides a more appropriate and valid attribution approach. We considered the option of proposing to remove the current version of the measure from the program and not proposing to replace it with a revised version. However, because we have developed and implemented only a handful of episode-based measures at this time, a substantial proportion of clinicians would be left with only MSPB clinician measure for the cost performance category. Because fewer than half of all clinicians in MIPS meet the case minimum for the MSPB clinician measure, and no other measure addresses the costs of primary care, we believe it is appropriate to use the best version of the total per capita cost measure available to us. While we recognize and value the MAP's expressed concerns regarding the revised measure specifications, we believe we have adequately addressed the mitigating factors through the information we have made publicly available (including testing results in the measure justification forms available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/macra-feedback.html*), as well as our discussions with stakeholders at the MAP and through further education and outreach activities. Thus, we are proposing to include the total per capita cost measure with these revised specifications in the cost performance category beginning with the CY 2020 performance period.

(C) Medicare Spending per Beneficiary Clinician Measure

Similar to the total per capita cost measure, we finalized the MSPB clinician measure for use in MIPS as an important measurement of clinician cost performance. Having been used in the Physician Value Modifier program, it had been tested and was reliable for Medicare populations and was familiar to the clinician community. However, when we finalized this measure for use in MIPS, we noted that as with all the cost measures, we would maintain this measure and update its specifications as appropriate (82 FR 53643). We continue to believe that the existing measure is appropriate to use in MIPS and continue to be committed to maintaining this cost measure with consideration of stakeholder input and testing. Hence, we re-evaluated the MSPB clinician measure as part of our routine measure maintenance. The re-evaluation was

informed by feedback received on this measure through prior public comment periods, as described in the CY 2017 Quality Payment Program final rule (81 FR 77017 through 77018) and the CY 2018 Quality Payment Program final rule (82 FR 53577 through 53578), as well as feedback that arose in the measure development contractor's discussions with the standing TEP during the process of re-evaluation. This feedback is summarized below:

- The attribution methodology did not recognize the team-based nature of inpatient care;
- The attribution based on the plurality of Part B service costs during index admission could potentially attribute episodes to specialties providing expensive services as opposed to those providing the overall care management for the patient; and
- The measure captured costs for services that are unlikely to be influenced by the clinician's care decisions.

The feedback summarized above informed the two modifications that we are proposing as part of the re-evaluation of this measure.

First, we are proposing to change the attribution methodology to distinguish between medical episodes (where the index admission has a medical MS–DRG) and surgical episodes (where the index admission has a surgical MS–DRG). A medical episode is first attributed to the TIN billing at least 30 percent of the inpatient E/M services on Part B physician/supplier claims during the inpatient stay. The episode is then attributed to any clinician in the TIN who billed at least one inpatient E/M service that was used to determine the episode's attribution to the TIN. A surgical episode is attributed to the surgeon(s) who performed any related surgical procedure during the inpatient stay, as determined by clinical input, as well as to the TIN under which the surgeon(s) billed for the procedure. The list of related surgical procedures MS–DRGs may be found in the measure codes list for the revised measure at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/mspb-clinician-zip-file.zip*. This revised attribution methodology accounts for the team-based nature of care provided when managing medical conditions during an inpatient stay and allows for attribution to multiple clinicians to ensure that all clinicians involved in a beneficiary's care are appropriately attributed.

Second, to account for the more limited influence clinicians' performance has on costs when compared with hospitals, we are proposing to add service exclusions to the measure to remove costs that are unlikely to be influenced by the clinician's care decisions. Specifically, we are proposing to exclude unrelated services specific to groups of MS–DRGs aggregated by major diagnostic categories (MDCs). Some examples of unrelated services include orthopedic procedures for episodes triggered by MS–DRGs under Disorders of Gastrointestinal System (MDC 06 and MDC 07) or valvular procedures for episodes triggered by MS–DRGs under Disorders of the Pulmonary System (MDC 04).

Further detail about these proposed changes to the measure is included in the measure specifications documents, which are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/mspb-clinician-zip-file.zip*. This includes a comparison of the proposed changes against the MSPB clinician measure as currently specified. A measure justification form containing testing results for this measure with the proposed revisions is available on the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*. We are proposing to include the revised MSPB clinician measure with these specifications in the cost performance category beginning with the CY 2020 performance period.

(vi) Reliability

(A) Reliability for Episode-Based Measures

In the CY 2017 QPP final rule (81 FR 77169 through 77170), we finalized a reliability threshold of 0.4 for measures in the cost performance category. In the CY 2019 PFS final rule, we established at § 414.1350(c)(4) and (5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures and 10 episodes for procedural episode-based measures (83 FR 59773 through 59774). We examined the reliability of the proposed 10 episode-based measures listed in Table 38 at our established case minimums and found that all of these measures meet the reliability threshold of 0.4 for the majority of groups at a case minimum of 10 episodes for procedural episode-based measures and 20 episodes for acute inpatient medical condition episode-based measures. All of the proposed measures meet this standard at the individual clinician level as well, with the exception of the Lower Gastrointestinal Hemorrhage episode-based measure. In section III.K.3.c.(2)(b)(vi)(B) of this proposed rule, we discuss a proposal to limit our assessment of certain cost measures to groups (identified by a TIN) based on the results of our reliability analysis.

TABLE 38—PERCENT OF TINS AND TIN/NPIS THAT MEET 0.4 RELIABILITY THRESHOLD

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Acute Kidney Injury Requiring New Inpatient Dialysis	100.0	0.58	85.3	0.48
Elective Primary Hip Arthroplasty	100.0	0.85	100.0	0.78
Femoral or Inguinal Hernia Repair	100.0	0.86	100.0	0.81
Hemodialysis Access Creation	93.1	0.63	70.1	0.48
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation	100.0	0.69	68.0	0.46
Lower Gastrointestinal Hemorrhage *	74.6	0.51	0.0	0.20
Lumbar Spine Fusion for Degenerative Disease, 1–3 Levels	100.0	0.77	100.0	0.69
Lumpectomy Partial Mastectomy, Simple Mastectomy	100.0	0.64	100.0	0.60
Non-Emergent Coronary Artery Bypass Graft (CABG)	100.0	0.82	100.0	0.74
Renal or Ureteral Stone Surgical Treatment	100.0	0.77	100.0	0.65

* This measure is being proposed only for groups. Please reference section III.K.3.c.(2)(b)(vi)(B) of the proposed rule.

(B) Limiting Assessment of Certain Measures to Groups

We have assessed clinicians and groups on cost measures when they meet the case minimum for a measure. As part of our efforts to ensure reliable measurement, we have examined the reliability of cost measures at the group and individual level, as clinicians are able to participate in MIPS in either way. However, for clinicians who participate in MIPS as individuals, we have found the proposed Lower Gastrointestinal Hemorrhage episode-based measure does not meet the reliability threshold of 0.4 that we established for measures in the cost performance category. While we considered not including the measure in MIPS for this reason, we do find that this measure meets the reliability threshold for those who participate in MIPS as part of a group. Therefore, we propose to include the measure in the cost performance category only for MIPS eligible clinicians who report as a group or virtual group. We will continue to assess the reliability of cost measures for group and individual participation as the measures are introduced or are revised. If we identify measures that are similarly found to meet our reliability threshold at the group level but not at the individual level, we would again consider limiting the assessment of the measure to groups.

(C) Reliability for Revised Cost Measures

In the CY 2017 Quality Payment Program final rule, we finalized a reliability threshold of 0.4 for measures in the cost performance category (81 FR 77169 through 77170). Additionally, we established a case minimum of 35 episodes for the MSPB clinician measure (81 FR 77171) and a case minimum of 20 beneficiaries for the total per capita cost measure (81 FR 77170). We codified these case minimums at § 414.1350(c)(1) and (2) in the CY 2019 PFS final rule (83 FR 59774). We based these case minimums on our interest in ensuring that the majority of clinicians and groups that were measured met the threshold of 0.4 reliability, which we felt best balanced our interest in ensuring moderate reliability without limiting participation. Given the significant changes to these measures that we are proposing in section III.K.3.c.(2)(b)(v), we again examined the reliability of the revised MSPB clinician and total per capita cost measures at these case minimums and found that the measures meet the reliability threshold of 0.4 for the majority of clinicians and groups at the existing case minimums, as shown in Table 39.

TABLE 39—PERCENT OF TINS AND TIN/NPIS THAT MEET 0.4 RELIABILITY THRESHOLD FOR THE REVISED MSPB CLINICIAN AND TOTAL PER CAPITA COST MEASURES

Measure name	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Medicare Spending Per Beneficiary Clinician	100.0	0.77	100.0	0.69
Total Per Capita Cost	100.0	0.82	100.0	0.89

Based on this analysis, in this proposed rule we are not proposing any changes to the case minimums, which we previously finalized as 35 for the MSPB clinician measure, and 20 for the total per capita cost measure.

(vii) Request for Comments on Future Potential Episode-Based Measure for Mental Health

We plan to continue to develop episode-based measures and propose to adopt them for the cost performance category in future rulemaking. As a part of these efforts, we seek to expand the range of procedures and conditions covered to ensure that more MIPS eligible clinicians have their cost performance assessed under clinically relevant episode-based measures. In recognition of the importance of assessing mental health care, we developed an acute inpatient medical condition episode-based measure for the treatment of inpatient psychoses and related conditions through the same process involving extensive expert clinician input as the measures proposed in section III.K.3.c.(2)(b)(vii) of this proposed rule. The specifications for the Psychoses/Related Conditions episode-based measure are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-revised-ebcm-measure-specs.zip*. The Psychoses/Related Conditions episode-based measure represents an opportunity to incentivize improvement in the field of mental health, a CMS priority area.

The Psychoses/Related Conditions episode-based measure was reviewed by the MAP Clinician Workgroup in December 2018 as part of a group with the 10 episode-based measures in Table 40 that we are proposing and received a preliminary recommendation of ''Conditional support for rulemaking,'' on the condition of NQF endorsement. In January 2019, The MAP Coordinating Committee pulled this measure for separate discussion from the other 10 episode-based measures and voted to finalize a recommendation of ''Do not support for rulemaking.'' The MAP's concerns with this measure related to: (i) The attribution model and its potential to hold clinicians responsible for costs outside of their influence; (ii) geographic variation in community resource availability; (iii) effects of physical comorbidities on measure score; and (iv) the potential to exacerbate access issues in mental health care. More detail is available in the 2019 MAP Clinician Workgroup final report at *http://www.qualityforum.org/Publications/2019/03/MAP_Clinicians_2019_Considerations_for_Implementing_Measures_Final_Report.aspx*.

We appreciate the feedback from the MAP but believe that the measure already accounts for these concerns. The expert workgroup convened by the measure development contractor to provide input on the specifications carefully considered these and other issues unique to mental health care throughout the development process and field testing. The expert workgroup, which reconvened to consider the MAP's concerns, noted that they had addressed each of the MAP's concerns during development activities and that this measure could be a significant step towards mental health parity by including psychiatry with other specialties in a MIPS episode-based measure. In addition, the measure provides opportunities for innovation in care coordination, which the Person and Family Committee expressed as an improvement need. We are now seeking

comments on the Psychoses/Related Conditions episode-based measure. In future years, we may propose the use of this measure.

Regarding the MAP's first concern about clinician accountability, the Psychoses/Related Conditions measure is constructed to only capture costs within an attributed clinician's influence through judicious service assignment rules. That is, services are only included in the cost of an episode when they meet specific conditions defined by procedure, diagnosis, and timing within the episode window. Members of the expert workgroup also noted that the measure can incentivize improved care coordination across care settings by holding clinicians accountable for certain post-discharge care. This recognition of the potential for measures to incentivize systems care coordination aligns with the rationale for quality measures currently available for reporting in MIPS, which acknowledge the goal of promoting shared accountability and collaboration with patients, families, and providers. For example, NQF #0576/Quality #391 Follow-Up After Hospitalization for Mental Illness (81 FR 77645) holds clinicians accountable for certain follow-up care.

Regarding the MAP's second concern about geographic variation, empirical analyses indicate the impact of geographic variation has limited effect on measure score and is similar across episode-based measures. The measure development contractor conducted empirical analyses to examine the effect of adding variables to the current risk adjustment model to account for state differences to assess the impact of geographic variation. The analyses indicated that there is a high correlation between the measure using the current risk adjustment model and the model accounting for state differences. At the TIN level, the correlation between the Psychoses/Related Conditions base measure and state-augmented measure is 0.838. At the TIN–NPI level, the correlation between the Psychoses/Related Conditions base measure and state-augmented measure is 0.835.

Regarding the MAP's third concern about physical comorbidities, the measure's risk adjustment model includes variables to account for patient comorbidities, including variables for patient history of other physical or mental health issues that might affect outcomes for patients captured under this measure.

Regarding the MAP's fourth concern about mental healthcare access, the large number of beneficiaries covered by this measure mitigates the potential for clinicians to limit access for Medicare patients. The potential coverage of beneficiaries is high, as there are approximately 102,000 beneficiaries with at least one episode (for episodes ending between January 1, 2017 and December 31, 2017). Additionally, the measure is designed to account for complex case mix to preserve access to care: The patient cohort is divided into sub-groups to ensure meaningful clinical comparisons between homogenous patient populations. We believe that this measure has the potential to incentivize improved care coordination and team-based care, and encourage the use of use community resources, which would improve access to care.

The Psychoses/Related Conditions episode-based measure would bridge the measurement gap in the MIPS cost performance category by providing mental health clinicians an episode-based measure as a complement to the two broader, population cost measures currently in MIPS. Based on episodes ending between January 1, 2017 and December 31, 2017, approximately 97 percent of MIPS eligible TINs and 36 percent of MIPS eligible TIN/NPIs meeting the 20 episode-case minimum for the Psychoses/Related Conditions measure also meet the case minimum for the revised MSPB clinician measure. Similarly, approximately, 98 percent of MIPS eligible TINs and 23 percent of MIPS eligible TIN/NPIs meeting the case minimum for the Psychoses/Related Conditions measure also meet the case minimum for the revised total per capita cost measure. We believe that this measure accurately reflects cost associated with inpatient psychiatrists' care and can provide information about cost performance that is actionable for mental health clinical practice as they provide clinicians with feedback on the cost of services within their reasonable influence.

A key goal for cost measures is to assess provider variation due to practice differences rather than chance, which can be determined by the measure's reliability. The Psychoses/Related Conditions measure tests well for reliability. The measure has a mean reliability over 0.7, generally considered the threshold for high reliability, at both TIN and TIN–NPI levels at the 10, 20, and 30-episode case minima. At the 20-epsiode case minimum imposed for acute inpatient medical condition episode-based measures, mean reliability is 0.83 for TIN and 0.88 for TIN–NPI level reporting, with 100.0 percent of TINs and 100.0 percent of TIN–NPIs meeting or exceeding the 0.4 threshold for moderate reliability. A measure justification form with additional testing results for this measure is available at the MACRA Feedback page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html*.

We are seeking comments on the potential use of this new Psychoses/Related Conditions episode-based measure in the cost performance category in a future MIPS performance period.

(viii) Summary of Previously Established and Proposed Measures for the Cost Performance Category for the 2020 and Future Performance Periods

TABLE 40—SUMMARY TABLE OF COST MEASURES FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS

Measure topic	Measure type	Measure Status
Total Per Capita Cost	Population-Based	Revised and proposed for 2020 performance period and beyond.
Medicare Spending Per Beneficiary Clinician	Population-Based	Revised and proposed for 2020 performance period and beyond.
Elective Outpatient Percutaneous Coronary Intervention (PCI).	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Knee Arthroplasty	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Revascularization for Lower Extremity Chronic Critical Limb Ischemia.	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.

TABLE 40—SUMMARY TABLE OF COST MEASURES FOR THE 2020 PERFORMANCE PERIOD AND FUTURE PERFORMANCE PERIODS—Continued

Measure topic	Measure type	Measure Status
Routine Cataract Removal with Intraocular Lens (IOL) Implantation.	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Screening/Surveillance Colonoscopy	Procedural episode-based	Currently in use for 2019 Performance Period and Beyond.
Intracranial Hemorrhage or Cerebral Infarction	Acute inpatient medical condition episode-based.	Currently in use for 2019 Performance Period and Beyond.
Simple Pneumonia with Hospitalization	Acute inpatient medical condition episode-based.	Currently in use for 2019 Performance Period and Beyond.
ST-Elevation Myocardial Infarction (STEMI) with Percutaneous Coronary Intervention (PCI).	Acute inpatient medical condition episode-based.	Currently in use for 2019 Performance Period and Beyond.
Acute Kidney Injury Requiring New Inpatient Dialysis.	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Elective Primary Hip Arthroplasty	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Femoral or Inguinal Hernia Repair	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Hemodialysis Access Creation	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation.	Acute inpatient medical condition episode-based.	Proposed for 2020 Performance Period and Beyond.
Lower Gastrointestinal Hemorrhage *(at group level only)*.	Acute inpatient medical condition episode-based.	Proposed for 2020 Performance Period and Beyond.
Lumbar Spine Fusion for Degenerative Disease, 1–3 Levels.	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Lumpectomy, Partial Mastectomy, Simple Mastectomy.	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Non-Emergent Coronary Artery Bypass Graft (CABG).	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.
Renal or Ureteral Stone Surgical Treatment	Procedural episode-based	Proposed for 2020 Performance Period and Beyond.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), and the CY 2019 PFS final rule (83 FR 59776 through 59777).

In this proposed rule, we are proposing to: (1) Modify the definition of rural area; (2) update § 414.1380(b)(3)(ii)(A) and (C) to remove the reference to the four listed accreditation organizations in order to be recognized as patient-centered medical homes and to remove the reference to the specific accrediting organization for comparable specialty practices; (3) increase the group reporting threshold to 50 percent; (4) establish factors to consider for removal of improvement activities from the Inventory; (5) remove 15, modify seven, and add two new improvement activities for the 2020 performance period and future years; and (6) conclude and remove the CMS Study on Factors Associated with Reporting Quality Measures. These proposals are discussed in more detail in this proposed rule.

(b) Small, Rural, or Health Professional Shortage Areas Practices

For our previously established policies regarding small, rural, or Health Professional Shortage Areas Practices, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77188), CY 2018 Quality Payment Program final rule (82 FR 53581), and § 414.1305. In the CY 2018 Quality Payment Program final rule (82 FR 53581 through 53582), we changed the definition of rural area at § 414.1305 to mean ZIP codes designated as rural, using the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available.

It has come to our attention that the rural area definition at § 414.1305 includes the incorrect file name for the rural designation. While we used the correct file, we just referenced it incorrectly. Therefore, we are proposing to update the MIPS rural area definition by correcting the file name. In the CY 2017 Quality Payment Program final rule (81 FR 77188), we incorrectly referenced the file we used for rural designation as ''*the most recent Health Resources and Services Administration (HRSA) Area Health Resource File data set available*'' instead of the correct file entitled ''*Federal Office of Rural Health Policy (FORHP) eligible ZIP codes*'' which may currently be found at *https://www.hrsa.gov/rural-health/about-us/definition/datafiles.html*. The HRSA Area Health Resources Files (AHRF) include data on Health Care Professions, Health Facilities, Population Characteristics, Economics, Health Professions Training, Hospital Utilization, Hospital Expenditures, and Environment at the county, state and national levels, from over 50 data sources [115] but does not contain specific data on rurality developed by HRSA's FORHP. To be clear, we have been using the more appropriate FORHP eligible ZIP code file in all previous 3 years of MIPS; we simply inadvertently listed the incorrect file name in the definition. Furthermore, the definition of rural in MIPS is based on the rural definition developed by HRSA's FORHP which may be found at *https://www.hrsa.gov/rural-health/about-us/definition/index.html*. The FORHP defines all non-Metro counties as rural and uses an additional method of determining rurality called the Rural-Urban

[115] *https://data.hrsa.gov/topics/health-workforce/ahrf*.

Commuting Area (RUCA) codes. The FORHP eligible ZIP codes are available in a file located at *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/aboutus/definition/forhp-eligible-zips.xlsx*. Therefore, we are proposing to modify the definition of rural area at § 414.1305 to mean a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available. We invite public comment on our proposal as discussed in this proposed rule.

(c) Patient-Centered Medical Home and Comparable Specialty Practice Accreditation Organizations

In the CY 2017 Quality Payment Program final rule (81 FR 77179 through 77180), we finalized at § 414.1380(b)(3)(ii) an expanded definition of what is acceptable for recognition as a certified-patient-centered medical home or comparable specialty practice. Specifically, we finalized that one of the criteria, as stated at § 414.1380(b)(3)(ii)(A), is whether the practice has received accreditation from one of four accreditation organizations that are nationally recognized; (A)(1) through (A)(4) lists the four organizations with nationally recognized patient-centered medical home accreditation programs: (1) The Accreditation Association for Ambulatory Health Care; (2) the National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home; (3) The Joint Commission Designation; or (4) the Utilization Review Accreditation Commission (URAC) (81 FR 77180). In addition, we finalized another criteria at § 414.1380(b)(3)(ii)(C), which states that the practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition (81 FR 77180). Further, we finalized that the criteria for being a nationally recognized accredited patient-centered medical home are that it must be national in scope and must have evidence of being used by a large number of medical organizations as the model for their patient-centered medical home (81 FR 77180).

Since finalizing these criteria, it has come to our attention that, we do not want to exclude other organizations. It was and is not our intention to limit patient-centered medical home or comparable specialty practice accreditation organizations to those listed. We realize that there may be additional accreditation organizations that have nationally recognized programs for accrediting patient-centered medical homes and comparable specialty practices that were not included. Therefore, we request comments on our proposal to update § 414.1380(b)(3)(ii)(A) and (C) to remove specific entity names.

(d) Improvement Activities Data Submission

We are proposing changes to the improvement activities data submission for group reporting requirements, as discussed below.

(i) Submission Mechanisms

For our previously established policies regarding improvement activities performance category submission mechanisms, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53650 through 53656), the CY 2019 PFS final rule (83 FR 59777), and § 414.1360(a)(1). We are not proposing any changes to these policies.

(ii) Submission Criteria

For our previously established policies regarding improvement activities performance category submission criteria, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77185), the CY 2018 Quality Payment Program final rule (82 FR 53651 through 53652), the CY 2019 PFS final rule (83 FR 59777 through 59778), and § 414.1380. We are not proposing any changes to these policies.

(iii) Group Reporting

In this proposed rule, we are making two proposals with respect to group reporting: (a) Increasing the group reporting threshold from at least one clinician to at least 50 percent of the group beginning with the 2020 performance year, and (b) at least 50 percent of a group's National Provider Identifiers (NPIs) must perform the same activity for the same continuous 90 days in the performance period beginning with the 2020 performance year. These are discussed in more detail below.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77181), in response to a public comment, we stated that if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period, the group may report on that activity. In addition, we specified that all MIPS eligible clinicians reporting as a group would receive the same score for the improvement activities performance category if at least one clinician within the group is performing the activity for a continuous 90 days in the performance period (81 FR 77181).

In the CY 2018 Quality Payment Program proposed rule (82 FR 30053), we requested comment for future consideration on issues related to whether we should establish a minimum threshold (for example, 50 percent) of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (Taxpayer Identification Number (TIN)) to receive credit in the improvement activities performance category in future years. Some commenters expressed concerns that setting a minimum threshold would add complexity or burden for clinicians. Other commenters supported the establishment of a minimum participation threshold in future years, noting that a minimum threshold will ensure scoring is reflective of care delivered by the group as a whole rather than one or a few high-performing clinicians.

We believe that by Year 4 (2020 performance year) of the Quality Payment Program, clinicians should be familiar with the improvement activities performance category. We believe that increasing the minimum threshold for a group to receive credit for the improvement activities performance category will not present additional complexity and burden for a group. With over 100 improvement activities available for eligible clinicians to choose from in the Improvement Activities Inventory, which may be found at the Quality Payment Program website *https://qpp.cms.gov/*, that provide a range of options for clinicians seeking to improve clinical practice that are not specific to practice size or specialty or practice setting, we believe that a group should be able to find applicable and meaningful activities to complete that would apply to at least 50 percent of individual MIPS eligible clinicians in a group.

Therefore, we are proposing to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the 2020 performance year and future years. We would like to note that if finalized the proposed changes to the group threshold would have no impact on the previously finalized policy that eligible clinicians participating in an APM will receive full points for the improvement activities performance category as discussed in the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260). This is an increase to the previously established requirement finalized in the CY 2017 Quality Payment Program final rule (81

FR 77181) that only one clinician within a TIN needs to attest to the completion of an improvement activity to get credit towards the MIPS final score. We believe a 50 percent threshold is achievable and appropriate because, if a group or virtual group has implemented an improvement activity, the activity should be recognized and adopted throughout much of the practice in order to improve clinical practice, care delivery, and outcomes. This aligns with our definition of an improvement activity at § 414.1305. In crafting our proposal, we also considered other thresholds, such as a lower threshold of 25 percent. However, we believe that improvement activities should be adopted throughout much of the practice to achieve improved outcomes. We do not believe that 25 percent group participation would reflect improved outcomes. We also considered a higher threshold of 100 percent, but have concerns that requiring every clinician within a group to perform improvement activities may be premature at this time because increasing the threshold by such a large amount may be considered burdensome to clinicians. However, we believe that 50 percent provides an appropriate balance between requiring at least half of the NPIs reporting as part of a group to participate in the improvement activities performance category and acknowledging the challenges to requiring every NPI in a group to perform the improvement activity for a group to receive credit. We also believe our proposal aligns with the 50 percent threshold for the number of practice sites that must be recognized for a TIN to receive full credit as a patient-centered medical home (82 FR 53655) and is both achievable and appropriate at this time.

Furthermore, we believe that requiring at least 50 percent of a group practice or TIN to perform an improvement activity for the same continuous 90-day performance period would facilitate improvement in clinical practice within a TIN. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77186), we considered setting the threshold for the minimum time required for performing an activity to longer periods up to a full calendar year. However, after researching several organizations we stated that we believed a minimum of 90 days is a reasonable amount of time (81 FR 77186). In addition, in response to comments we stated that we believed that each activity can be performed for a full 90 consecutive days by some, if not all, MIPS eligible clinicians, and that there are a sufficient number of activities included that any eligible clinician may select and perform for a continuous 90 days that will allow them to successfully report under this performance category (81 FR 77186).

Therefore, we are requesting comments on our proposal to revise § 414.1360(a)(2) to state that beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. To be clear, other submission requirements would remain the same. In other words, each TIN would need to submit an attestation for each improvement activity selected that at least 50 percent of its NPIs performed the same activity for the same continuous 90 days in the performance period. For example, TIN 1234 attests that at least 50 percent of its NPIs performed the improvement activity entitled: ''Participation in a QCDR that promotes use of patient engagement tools'' (IA_BE_7) for the same continuous 90-day period. Because IA_BE_7 is medium-weighted, the example TIN would receive 10 points toward the total possible improvement activities score. TIN 1234 also attests that at least 50 percent of its NPIs performed the improvement activity entitled: ''Implementation of formal quality improvement methods, practice changes, or other practice improvement processes'' (IA_PSPA_19) for the same continuous 90-day period. Because IA_PSPA_19 is medium-weighted, the example TIN would receive another 10 points toward the total possible improvement activities score. We refer readers to the CY 2019 Quality Payment Program final rule (83 FR 59753 through 59754) where we discuss the data submission deadline which was finalized at § 414.1325(e)(1) as follows: For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

We invite public comments on our proposal as discussed above, as well as the alternatives considered.

(e) Improvement Activities Inventory

We are proposing changes to the Improvement Activities Inventory to: (1) Establish removal factors to consider when proposing to remove improvement activities from the Inventory; (2) remove 15 improvement activities for the 2020 performance period and future years contingent on our proposed removal factors being finalized; (3) modify seven existing improvement activities for the 2020 performance period and future years; and (4) add two new improvement activities for the 2020 performance period and future years. These proposals are discussed in more detail in this proposed rule.

(i) Proposed Factors for Consideration in Removing Improvement Activities

In the CY 2017 Quality Payment Program final rule (82 FR 53660 through 53661), we discussed that in future years, we anticipated developing a process and establishing factors for identifying activities for removal from the Improvement Activities Inventory through the Annual Call for Activities process. In the CY 2018 Quality Payment Program proposed rule (82 FR 30056), we invited public comments on what criteria should be used to identify improvement activities for removal from the Inventory. A few commenters did not support the idea of establishing removal factors for improvement activities, believing that many practices have made financial investments to perform these activities and that no activities should be removed. Some commenters suggested that we should remove activities that: Have become obsolete, are topped out, do not show demonstrated improvements over time, or are not attested to for three consecutive years. The commenters recommended that their removal should be conducted using an approach similar to what is used for the removal of quality measures. In our responses, we stated that we appreciate the commenters input. In addition, we understand that many practices may have made financial investments to perform these activities, but believe that over time, certain improvement activities should be considered for removal to ensure the list is robust and relevant. We will fully examine each activity prior to removal. In addition, we stated that commenters would have an opportunity to provide their input during notice-and-comment rulemaking. We agreed with commenters that we should remove activities as needed and should consider the removal criteria already established for quality measures. We continue to believe that having factors to consider in removing improvement activities would provide transparency and alignment with the removal of quality measures. Therefore, we are proposing to adopt the following factors for our consideration when

proposing the removal of an improvement activity:

- Factor 1: Activity is duplicative of another activity;
- Factor 2: There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice;
- Factor 3: Activity does not align with current clinical guidelines or practice;
- Factor 4: Activity does not align with at least one meaningful measures area;
- Factor 5: Activity does not align with the quality, cost, or Promoting Interoperability performance categories;
- Factor 6: There have been no attestations of the activity for 3 consecutive years; or
- Factor 7: Activity is obsolete.

These factors directly reflect those already finalized for quality measures found in the CY 2019 PFS final rule (83 FR 59765). The removal of improvement activities from the Inventory, including discussion of the removal factor(s) considered, would occur through notice-and-comment rulemaking. We note that these removal factors are considerations taken into account when deciding whether or not to remove improvement activities; but they are not firm requirements.

Therefore, we invite public comments on our proposal to implement factors to consider in removing improvement activities from the Inventory. In conjunction with this proposal, we are proposing a number of improvement activity removals as discussed in the next section and in Appendix 2 of this proposed rule. Those removals are contingent upon finalization of these removal factors.

(ii) New Improvement Activities and Modifications to and Removal of Existing Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities or modifications to existing improvement activities to the Improvement Activities Inventory through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), and Tables X and G in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303) for our previously finalized Improvement Activities Inventory. We also refer readers to the Quality Payment Program website at *https://qpp.cms.gov/* for a complete list of the most current list of improvement activities. In this proposed rule, we invite comments on our proposals to: (1) Remove 15 improvement activities from the Inventory beginning with the 2020 performance period, (2) modify seven existing improvement activities for 2020 performance period and future years, and (3) add two new improvement activities for 2020 performance period and future years. We refer readers to Appendix 2 of this proposed rule for further details. Our proposals to remove improvement activities are being made in conjunction with our proposal to adopt removal factors and are contingent upon finalization of that proposal.

(f) CMS Study on Factors Associated With Reporting Quality Measures

In this proposed rule, we are proposing to end this study and concurrently, remove the incentive under the improvement activity performance category that this study provided for study participants.

(i) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77195), we created the Study on Improvement Activities and Measurement. In our quest to create a culture of improvement using evidence-based medicine on a consistent basis, we believe fully understanding the strengths and limitations of the current processes of collecting and submitting quality measurement data is crucial to better understand and improve these current processes. We proposed to conduct a study on clinical improvement activities and measurement to examine clinical quality workflows and data capture using a simpler approach to quality measures (81 FR 77195). In the CY 2018 Quality Payment Program final rule (82 FR 53662) and CY 2019 PFS final rule (83 FR 59783), we finalized updates to the study.

Starting in CY 2017, this annual study was slated for a minimum period of 3 years, as stated in CY 2019 PFS final rule (83 FR 59776). Study participants were recruited every study year. The study population started in CY 2017 with a minimum of 42 individuals (81 FR 77195), grew to a minimum of 102 individuals for CY 2018 (82 FR 53662) and 200 individuals for CY 2019 (83 FR 59783). Each years' study population is comprised of the following categories: Urban versus non-urban, groups and individual clinicians; clinicians reporting quality measures in groups or reporting individually, different practice sizes; and different specialty groups (81 FR 77195). These changes to the study sample size over the years provided data for the study's analysis. The goals of the study are to see whether there will be improved outcomes, reduced burden in reporting, and enhancements in clinical care by selected MIPS eligible clinicians desiring: A more data driven approach to quality measurement, measure selection unconstrained by a CEHRT program or system, improving data quality submitted to CMS, enabling CMS get data more frequently and provide feedback more often (81 FR 77195). To encourage participation by clinicians and counterbalance clinician burden for anticipation of study, participating clinicians were incentivized with full improvement activity credit as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195 through 77197).

(ii) Proposal To End and Remove Study

We believe by the end of 2020 we will have reached the minimum sample size and have accrued the minimum data needed for the analysis to achieve the study goals. Therefore, we request comments on our proposal to conclude this study at the end of the CY 2019 performance period. In conjunction with our proposal to end the study, we are also proposing to remove the study and the incentive provided towards the improvement activity performance category beginning with the 2020 performance period. If the study is ended as proposed above, we are proposing to remove this activity because it would be obsolete (proposed removal factor 7). As a result, the full improvement activity credit given to participants as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77195–77197), would no longer be available starting with the 2020 performance period.

(iii) Future Steps

After completing this data collection phase, we next plan to analyze the data gathered (which include lessons learned) and to make recommendations to improve outcomes, reduce burden, and enhance clinical care. We plan to finish the final data analysis by Spring 2020. This analysis would contain all the study years. It would show the trends and associations of all the factors we examined. It would also show the lessons learnt by study participants over the 3 years of the study. At the conclusion of this study and after analysis of the results, we plan to shift our focus to implementation of recommendations. We intend for this to include feedback to clinicians and stakeholders and educational and

outreach work. We plan to undertake education and outreach to the public. We would also include the results in other Quality Payment Program educational materials such as webinars.

(4) Promoting Interoperability

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of Certified Electronic Health Record Technology (CEHRT) as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the Advancing Care Information performance category, and it was reported by MIPS eligible clinicians as part of the overall MIPS program. In 2018, we renamed the Advancing Care Information performance category as the Promoting Interoperability performance category (83 FR 35912). As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

For the Promoting Interoperability performance category, our proposals include: (1) For the 2023 MIPS payment year, establishing a performance period of a minimum of a continuous 90-day period within CY 2021, up to and including the full calendar year; (2) making the Query of Prescription Drug Monitoring Program (PDMP) measure optional in CY 2020, and in the event we finalize this proposal, making the e-Prescribing measure worth up to 10 points in CY 2020; (3) removing the numerator and denominator for the Query of PDMP measure and instead requiring a ''yes/no'' response beginning in CY 2019; (4) removing the Verify Opioid Treatment Agreement measure beginning in CY 2020; (5) redistributing the points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to Their Health Information measure if an exclusion is claimed, beginning in CY 2019; (6) revising the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion to more clearly and precisely capture our intended policy, beginning in CY 2019; (7) continuing the existing policy of reweighting the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians for the performance period in 2020; and (8) proposals related to hospital-based MIPS eligible clinicians and non-patient facing MIPS eligible clinicians in groups.

These proposals are discussed in more detail in this proposed rule.

We are also seeking input through Requests for Information as follows: (1) Potential Opioid Measures for Future Inclusion in the Promoting Interoperability performance category, (2) NQF and CDC Opioid Quality Measures, (3) a Metric to Improve Efficiency of Providers within EHRs, (4) the Provider to Patient Exchange Objective, (5) Integration of Patient-Generated Health Data into EHRs Using CEHRT, and (6) Engaging in Activities that Promote the Safety of the EHR.

(b) Goals of Proposed Changes to the Promoting Interoperability Performance Category

As we look toward the future of the Promoting Interoperability performance category, the general goals of our proposals in this proposed rule center on: (1) A priority of stability within the performance category after the recent changes made in the CY 2019 PFS final rule (83 FR 59785 through 59820) while continuing to further interoperability through the use of CEHRT; (2) reducing administrative burden; (3) continued use of the 2015 Edition CEHRT; (4) improving patient access to their EHRs so they can make fully informed health care decisions; and (5) continued alignment with the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, where appropriate.

(c) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2019 PFS final rule at § 414.1320(e)(1) (83 FR 59745 through 59747), for purposes of the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2022 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2020, up to and including the full CY 2020 (January 1, 2020 through December 31, 2020).

For the 2023 MIPS payment year, we are proposing to add § 414.1320(f)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (CY 2021). This proposal aligns with the proposed EHR reporting period in CY 2021 for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (84 FR 19554). We believe this would be an appropriate performance period because of the maturation needed within the performance category, including the changes to measures and other changes being proposed in this rule. In addition, it would offer stability and continuity for the Promoting Interoperability performance category after the performance category overhaul that was finalized in the CY 2019 PFS final rule (83 FR 59785 through 59820).

We are requesting comments on this proposal.

(d) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Proposed Changes to Measures for the e-Prescribing Objective

(A) Background

Beginning with the MIPS performance period in 2019, we adopted two new measures for the e-Prescribing objective that are based on electronic prescriptions for controlled substances: (1) Query of Prescription Drug Monitoring Program (PDMP) (83 FR 59800 through 59803); and (2) Verify Opioid Treatment Agreement (83 FR 59803 through 59806). These measures built upon the meaningful use of CEHRT, as well as the security of electronic prescribing of Schedule II controlled substances while preventing diversion. For both measures, we defined opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence. Additionally, we noted the intent of the new measures was not to dissuade the prescribing or use of opioids for patients with medical diagnoses or conditions that benefit from their use, such as patients diagnosed with cancer or those receiving hospice.

During the comment period for the CY 2019 PFS proposed rule (83 FR 35921 through 35925), and subsequently through public forums and correspondence, we received extensive comments from stakeholders regarding the Query of PDMP measure and the Verify Opioid Treatment Agreement measure. While this feedback is the main catalyst for our proposals, there have also been significant legislative changes that have the potential to

positively impact the Promoting Interoperability performance category, specifically the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018). This legislation was enacted to address the opioid crisis and affects a wide range of HHS programs and policies. While this legislation is not the main reason for our proposals, we believe it may significantly affect the maturation, requirements, and use of PDMPs and State networks upon which the Query of PDMP measure is dependent.

In this proposed rule, we are aiming to be responsive to the comments that we have received from stakeholders since the CY 2019 PFS final rule was published and to take into account certain aspects of the SUPPORT Act that may have implications for the policy goals of the Promoting Interoperability performance category.

As explained in further detail below, we are proposing to make the Query of PDMP measure optional in CY 2020, remove the numerator and denominator that we established for the Query of PDMP measure and instead require a ''yes/no'' response beginning in CY 2019, and remove the Verify Opioid Treatment Agreement measure beginning in CY 2020. In section III.K.3.c.(4)(d)(i) of this proposed rule, we are also requesting information on potential new opioid use disorder (OUD) prevention and treatment-related measures. We believe the requests for information will help to inform future rulemaking and not only help prevent and treat substance use disorder, but allow us to adopt measures that enable flexibility without added burden for clinicians. We value stakeholders' continued interest in and support for combating the nation's opioid epidemic.

(B) Query of Prescription Drug Monitoring Program (PDMP) Measure

(aa) Query of PDMP Measure

As we stated in the CY 2019 PFS final rule (83 FR 59800 through 59803), the Query of PDMP measure is optional and available for bonus points for the 2019 performance period, and we will propose our policy for the Query of a PDMP measure for the 2020 performance period in future rulemaking. We afforded MIPS eligible clinicians' flexibility for implementing this measure, including the flexibility to query the PDMP in any manner allowed under their State law.

However, we have received substantial feedback from health IT vendors and specialty societies that this flexibility presents unintended challenges, such as the significant burden associated with IT system design and development needed to accommodate the measure and any future changes to it. During the CY 2019 PFS proposed rule comment period (83 FR 35922 through 35925) and after the final rule was published, these stakeholders stated that it is premature to require the Query of PDMP measure in the 2020 performance period especially given the maturation needed in PDMP development.

We agree with stakeholders that PDMPs are still maturing in their development and use. In addition there is considerable variation among state PDMP programs as many only operate within a state and are not linked to larger systems. For more information, we refer readers to the following: The National Alliance of Model State Drug Laws (*https://namsdl.org/topics/pdmp/*) and PDMP Training and Technical Assistance Center (*https://www.pdmpassist.org/content/pdmp-maps-and-tables*).

Stakeholders also mentioned the challenge posed by the current lack of integration of PDMPs into the EHR workflow. Historically, health care providers have had to go outside of the EHR workflow in order to separately log in to and access the State PDMP. In addition, stakeholders noted the wide variation in whether PDMP data can be stored in the EHR. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. ONC is currently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across States. This assessment is exploring factors like PDMP data integration, standards and hubs used to facilitate interstate PMDP data exchange, access permissions, and laws and regulations governing PDMP data storage.

In October 2018, the SUPPORT Act became law, signifying an important investment and approach for our nation in combating the opioid epidemic. The provisions of this law aim to provide for opioid use disorder prevention, recovery, and treatment and aim to increase access to evidence-based treatment and follow-up care included through legislative changes specific to the Medicare and Medicaid programs. Specifically, with respect to PDMPs, the SUPPORT Act includes new requirements and federal funding for PDMP enhancement, integration, and interoperability, and establishes mandatory use of PDMPs by certain Medicaid providers, in an effort to help reduce opioid misuse and overprescribing, and in an effort to help promote the overall effective prevention and treatment of opioid use disorder.

Section 5042(a) of the SUPPORT Act added section 1944 to the Act, titled ''Requirements relating to qualified prescription drug monitoring programs and prescribing certain controlled substances.'' This section increases federal Medicaid matching rates during FY 2019 and 2020 for certain state expenditures relating to qualified PDMPs administered by states. Under section 1944(b)(1) of the Act, to be a qualified PDMP, a PDMP must facilitate access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible: Information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period; and the name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at the least the most recent 12-month period. Under section 1944(b)(2) of the Act, a qualified PDMP must also facilitate the integration of the information described in section 1944(b)(1) of the Act into the workflow of a covered provider, which may include the electronic system used by the covered provider for prescribing controlled substances.

Section 1944(f) of the Act establishes, for FY 2019 and FY 2020, a 100 percent federal Medicaid matching rate for state expenditures to design, develop, or implement a PDMP that meets the requirements outlined in section 1944(b)(1) and (2) of the Act, and to make connections to that PDMP. Section 1944(f)(2) of the Act specifies that, to qualify for the 100 percent federal matching rate, a state must have in place agreements with all contiguous states that, when combined, enable covered providers in all the contiguous states to access, through the PDMP, all information described in 1944(b)(1) of the Act.

Section 5042(b) of the SUPPORT Act requires CMS, in consultation with the Centers for Disease Control and Prevention (CDC), to issue guidance not later than October 1, 2019 on best practices on the uses of PDMPs required of prescribers and on protecting the

privacy of Medicaid beneficiary information maintained in and accessed through PDMPs. Furthermore, section 5042(c) of the SUPPORT Act requires that HHS develop and publish, not later than October 1, 2020, model practices to assist State Medicaid program operations in identifying and implementing strategies to utilize data-sharing agreements described in section 1944(b) of the Act for the following purposes: Monitoring and preventing fraud, waste, and abuse; and improving health care for individuals enrolled in Medicaid who transition in and out of Medicaid coverage, who may have sources of health care coverage in addition to Medicaid coverage, or who pay for prescription drugs with cash. We note that section 7162 of the SUPPORT Act also supports PDMP integration as part of the CDC's grant programs aimed at efficiency and enhancement by states, including improvement in the intrastate and interstate interoperability of PDMPs.

In addition, the explanatory statement that accompanied Title II of Division H of the Consolidated Appropriations Act, 2018 (Pub. L. 115–141),[116] encouraged the CDC to work with the ONC to enhance the integration of PDMPs and EHRs. As part of this effort, the CDC and ONC are collaborating to expand upon previous and leverage input from current federal efforts to advance and scale PDMP integration with health IT systems. This collaboration includes testing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs, and incorporating policy considerations, as relevant, to inform the implementation and success of integration approaches.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to allow only a single workflow. At the same time, we have heard extensive feedback from EHR developers that incorporating the ability to count the number of PDMP queries in CEHRT would require more robust certification specifications and standards. These stakeholders state that health IT developers may face significant cost burdens under the current flexibility allowed for health care providers if they fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Developers have indicated that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure.

Given the stakeholder concerns discussed above regarding the lack of integration, the recent enactment of the SUPPORT Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), and the activities funded by the CDC, we believe that additional time is needed to evaluate the changing PDMP landscape prior to requiring a Query of PDMP measure, or introducing requirements related to EHR–PDMP integration.

Therefore, we are proposing to make the Query of PDMP measure optional and eligible for 5 bonus points for the Electronic Prescribing objective in CY 2020. Making the measure optional in CY 2020 would allow time for further integration of PDMPs and EHRs to minimize the burden on MIPS eligible clinicians reporting this measure while still giving clinicians an opportunity to report on and earn points for the measure. We are proposing that, in the event we finalize this proposal for the Query of PDMP measure, the e-Prescribing measure would be worth up to 10 points in CY 2020.

In addition, beginning with the 2019 performance period, we are proposing to remove the numerator and denominator that we established for the Query of PDMP measure in the CY 2019 PFS final rule (83 FR 59800 through 59803) and instead require a ''yes/no'' response. Under this proposal, the measure description would remain the same (83 FR 59803), but instead of submitting numerator and denominator information for the measure, MIPS eligible clinicians would submit a ''yes/no'' response. A ''yes'' response would indicate that for at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. We are proposing this change to give us more time to restructure the measure and develop a robust measure that meets the needs of both health care providers and other stakeholders. Because currently there are not standards-based interfaces between CEHRT and PDMPs, health care providers must manually track the number of times that they query a PDMP outside of CEHRT. We are proposing this change to reduce the burden on health care providers of having to manually keep track of information related to the measure and to mitigate the burden on health IT developers who would otherwise have to develop the measure's numerator and denominator calculations when we expect to propose changes to the measure in the near future. Therefore, health care providers and health IT developers have suggested that, given the current state, there would be a significant reduction in burden by allowing health care providers to satisfy the measure by submitting a ''yes/no'' response, rather than reporting a numerator and denominator. In addition, for the 2019 performance period, the Query of PDMP measure is not scored based on a clinician's performance as determined by a numerator and denominator; instead, it is an optional measure that is eligible for a full five bonus points regardless of how a clinician performs (83 FR 59794 through 59795). Thus, because the measure is not scored based on performance, requiring a ''yes/no'' response instead of a numerator and denominator would not affect the potential number of points that a clinician could earn by reporting on the measure.

We do not believe that these changes would result in additional costs (time or money) for health care providers, and instead would reduce the burden of manually tracking information needed to report on this measure in its current form. For CY 2019, we did not provide exclusions for the Query of PDMP and Verify Opioid Treatment Agreement measures because they were optional and eligible for bonus points, and similarly, we do not believe exclusions would be necessary for the Query of PDMP measure if we finalize our proposal to make the measure optional and eligible for bonus points in CY 2020.

We also welcome comments on future timing for requiring a measure that includes EHR–PDMP integration and on the value of the measure for advancing the effective prevention and treatment of opioid use disorder especially in relation to the requirements of the SUPPORT Act described above.

We also note that some stakeholders have requested that we define a value set for controlled substances for the opioid-related measures, Query of

[116] *https://www.govinfo.gov/content/pkg/CREC-2018-03-22/html/CREC-2018-03-22-pt3-PgH2697.htm.*

PDMP and Verify Opioid Treatment Agreement. In the CY 2019 PFS final rule (83 FR 59803), for the Query of PDMP and Verify Opioid Treatment Agreement measures, we defined opioids as Schedule II controlled substances under 21 CFR 1308.12. We recognize that some challenges remain related to electronic prescribing of controlled substances, including more restrictive state laws and lack of products both for health care providers and pharmacies that include the necessary functionalities. We anticipate working closely with the Drug Enforcement Administration (DEA) on future technical requirements that can better support measurement of adoption and use of electronic prescribing of controlled substances, which may include the definition of a value set related to such measures. As more information on developing technical requirements becomes available, we will provide additional information.

As we seek comment and continue to advance this measure, we are excited about future innovations that may help improve PDMPs and support the electronic prescribing of controlled substances. We envision a future state where PDMP data is integrated into the clinical workflow and where clinicians do not have to access multiple systems to find and reconcile the information. While we may have a long distance to go to get to this state, we believe that it is an achievable goal for the future of the Promoting Interoperability performance category.

We are inviting comments on these proposals.

(C) Verify Opioid Treatment Agreement Measure

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we finalized the Verify Opioid Treatment Agreement measure as optional in both CYs 2019 and 2020. Since we proposed this measure, we have received feedback from stakeholders that this measure has presented significant implementation challenges and an increase in burden, and does not further interoperability. Below, we outline some of the ongoing concerns we heard since the measure was finalized in the CY 2019 PFS final rule (83 FR 59803 through 59806).

(aa) Lack of Certification Standards and Criteria

Stakeholders have continually expressed concern regarding the lack of defined data elements, structure, standards and criteria for the electronic exchange of opioid treatment agreements and how this impacts verifying whether there is an opioid treatment agreement to meet this measure. We acknowledged these concerns in the CY 2019 PFS final rule (83 FR 59803 through 59806).

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we stated that there are a number of ways that certified health IT may be able to support the electronic exchange of opioid abuse-related treatment data such as the care plan template within the Consolidated-Clinical Document Architecture (C–CDA). We stated this information could be considered as part of an opioid treatment agreement, even though we did not define the elements of one. However, we understand that while such standards may include relevant information, the lack of clarity around a specific standard to support incorporation of an opioid treatment agreement presents an additional source of burden to clinicians seeking to report on the measure.

(bb) Calculating 30 Cumulative Day Look-Back Period

Another area where stakeholders have expressed concern is how to calculate 30 cumulative days of opioid prescriptions in a 6-month period. One possible solution we offered was to utilize the NCPDP 10.6 Medication History query. In the CY 2019 PFS final rule (83 FR 59803 through 59806), we noted that the Medication History query does not contain a discrete field for prescription days and relies on third party data that may not be discrete. Since the CY 2019 PFS final rule was published, stakeholders have continued to express this concern and impress upon us that the 30-cumulative day total in a 6-month look-back period cannot be automatically calculated, requiring health care providers to engage in a burdensome, manual calculation process if they wish to report on this measure.

In addition, we have heard concerns over which medications should be used to determine the 30-cumulative day threshold. For example, stakeholders were unsure if medications given while a patient is admitted to the hospital should count towards the 30 cumulative days and also how as needed, or PRN, medications should be addressed.

Stakeholders have also indicated that this measure could present timing challenges. For example, it may cause patients being discharged on opioids to be delayed in their discharge to account for the possible time-consuming nature of having to search for an opioid treatment agreement.

(cc) Unintended Burden Caused by Flexibility

In the CY 2019 PFS final rule (83 FR 59803 through 59806), we chose not to define what constitutes an opioid treatment agreement. While we believed that this would allow flexibility for health care providers to determine which elements they believed were most important to an opioid treatment agreement, we have heard from stakeholders that the lack of definition and standards around what would constitute an opioid treatment agreement has created an unintended burden. Specifically, some stakeholders indicated that we should define an opioid treatment agreement so that MIPS eligible clinicians would have a standardized definition of an opioid treatment agreement and the criteria to make up an opioid treatment agreement. However, other stakeholders indicated that given the lack of consensus within the industry on what should or should not be included in an opioid treatment agreement and on the clinical efficacy of various options for such agreements, that it would be inappropriate for us to define what should constitute an opioid treatment agreement at this time.

We have heard from stakeholders that the challenges described above result in a measure that is vague, burdensome to measure and does not necessarily offer a clinical value to the health care providers or support the clinical goal of supporting OUD treatment. Therefore, we are proposing to remove the Verify Opioid Treatment Agreement measure from the Promoting Interoperability performance category beginning with the performance period in CY 2020.

While we are proposing to remove the Verify Opioid Treatment Agreement measure, we believe there may be other opioid measures that would be more effective in combatting the opioid epidemic, offer value for health care providers in measuring the impacts of health IT-enabled resources on OUD prevention and treatment, and engage patients in care coordination and planning. We are seeking public comment on a series of question in requests for information regarding new opioid measures in section III.K.3.c(4)(d)(i) of this proposed rule.

We invite comments on this proposal.

(ii) Health Information Exchange Objective

There are two measures under the Health Information Exchange objective: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating

Health Information Measure. We are proposing minor modifications to both measures.

(A) Proposed Modification of the Support Electronic Referral Loops by Sending Health Information Measure

In the CY 2019 PFS final rule (83 FR 59807 through 59808), we renamed the Send a Summary of Care measure to the Support Electronic Referral Loops by Sending Health Information measure. Although an exclusion is available for this measure (83 FR 59808), we acknowledged that we did not address in the CY 2019 PFS proposed rule how the points for the measure would be redistributed in the event the exclusion is claimed, and stated that we intended to propose a redistribution policy in next year's rulemaking (83 FR 59795). Accordingly, we are proposing to redistribute the points for the Support Electronic Referral Loops by Sending Health Information measure to the Provide Patients Access to Their Health Information measure if an exclusion is claimed. We have chosen to redistribute the points to the Provide Patients Access to Their Health Information measure because we believe that many MIPS eligible clinicians may be eligible to claim exclusions for both measures under the Health Information Exchange objective. Under our existing policy (83 FR 59788), if an exclusion is claimed for the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, the 20 points associated with it will be redistributed to the Support Electronic Referral Loops by Sending Health Information measure. Under our proposal, if exclusions are claimed for both the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the Support Electronic Referral Loops by Sending Health Information measure, the 40 points associated with these measures would be redistributed to the Provide Patients Access to Their Health Information measure. We are proposing that this redistribution policy would be applicable beginning with the 2019 performance period/2021 MIPS payment year.

We invite comments on this proposal.

(B) Modification of the Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the CY 2019 PFS final rule (83 FR 59808 through 59812), we replaced the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure with a new measure called the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. We established the following exclusion for the new measure: Any MIPS eligible clinician who receives fewer than 100 transitions of care or referrals or has fewer than 100 encounters with patients never before encountered during the performance period would be excluded from this measure (83 FR 59812). We are proposing to revise this description of the exclusion to more clearly and precisely capture our intended policy. The Request/Accept Summary of Care measure, which as noted previously was replaced by the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, included the following exclusion: Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period (83 FR 59798, 82 FR 53679 through 53680). Our intention was to use that same exclusion from the Request/Accept Summary of Care measure for the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. Instead, the description of the exclusion that we included in the CY 2019 PFS final rule (83 FR 59812) did not precisely track the description of the Request/Accept Summary of Care measure exclusion, and could be construed in a way that would make the exclusion more difficult for a MIPS eligible clinician to meet. Specifically, it could be read to create two different sets of exclusion criteria: Receiving fewer than 100 transitions of care or referrals; or having fewer than 100 encounters with patients never before encountered. This was not our intention. Rather, as with the Request/Accept Summary of Care measure exclusion, our intention was that a combination of the two criteria must occur fewer than 100 times during the performance period for the exclusion to be applicable to a MIPS eligible clinician. Thus, we are proposing to revise the description of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure exclusion to track the description of the Request/Accept Summary of Care measure exclusion (83 FR 59798, 82 FR 53679 through 53680): Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period. For example, during the performance period, if a MIPS eligible clinician received 50 transitions of care, 50 referrals, and 50 patient encounters in which they have never before encountered the patient, the total sum of 150 would be above the threshold of fewer than 100 times, and therefore the MIPS eligible clinician would not be eligible for this exclusion. We are proposing that the revised description of the exclusion would be applicable beginning with the 2019 performance period/2021 MIPS payment year.

For ease of reference, Table 41 lists the objectives and measures for the Promoting Interoperability performance category for the 2020 performance period as revised to reflect the proposals made in this proposed rule. For more information on the 2015 Edition certification criteria required to meet the objectives and measures, we refer readers to Table 43 in the CY 2019 PFS final rule (83 FR 59817).

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TABLE 41: Objectives and Measures for the Promoting Interoperability Performance Category in 2020

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing: Generate and transmit permissible prescriptions electronically.	Query of PDMP (bonus): For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.				
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of CEHRT.	Support Electronic Referral Loops by Receiving and Incorporating Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	transmit his or her health information; and 2.The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health	Syndromic Surveillance Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician 1.Is not in a category of health care providers from which ambulatory syndromic data is collected by their jurisdiction's syndromic surveillance system; OR 2.operates in a jurisdiction for which no public health

Objective	Measure	Numerator	Denominator	Exclusion
agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	surveillance data from an urgent care setting.			agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from MIPS eligible clinicians as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable	Public Health Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not diagnose or directly treat any disease or condition associated with a public health registry in the MIPS eligible clinician's jurisdiction during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no public health registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry

Objective	Measure	Numerator	Denominator	Exclusion
law and practice.				transactions as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Clinical Data Registry Reporting: The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician 1. Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the performance period; OR 2.operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3.operates in a jurisdiction where no clinical data registry for which the MIPS eligible clinician is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the performance period.

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(e) Scoring Methodology

(i) Proposed Changes to the Scoring Methodology for the 2020 Performance Period

In the CY 2019 PFS final rule (83 FR 59785 through 59796), we finalized a new performance-based scoring methodology for the Promoting Interoperability performance category beginning with the performance period in 2019. As previously discussed in section III.K.3.c.(4)(d)(i) of this proposed rule, we are proposing to: (1) Make the Query of PDMP measure optional and eligible for five bonus points in CY 2020; (2) make the e-Prescribing measure worth up to 10 points in CY 2020, in the event we finalize the proposal for the Query of PDMP measure; and (3) remove the Verify Opioid Treatment Agreement measure beginning in 2020. Table 42 reflects these proposals, although the maximum points available do not include points that would be redistributed in the event that an exclusion is claimed.

TABLE 42: Proposed Scoring Methodology for the Performance Period in 2020

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing**	10 points
	Query of PDMP	5 points (*bonus*)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information**	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information**	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registry Reporting** Electronic Case Reporting** Public Health Registry Reporting** Clinical Data Registry Reporting** Syndromic Surveillance Reporting**	10 points

** Exclusion available.

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(f) Additional Considerations

(i) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In prior rulemaking (83 FR 59818 through 59819), we discussed our belief that certain types of MIPS eligible clinicians (NPs, PAs, CNSs, and CRNAs) may lack experience with the adoption and use of CEHRT. Because many of these non-physician clinicians were or are not eligible to participate in the Medicare or Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), we stated that we have little evidence as to whether there are sufficient measures applicable and available to these types of MIPS eligible clinicians under the advancing care information (now known as Promoting Interoperability) performance category. We established a policy at § 414.1380(c)(2)(i)(A)(5) for the performance periods in 2017, 2018, and 2019 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act. We stated our intention to use data from the first performance period (2017) to further evaluate the participation of these MIPS eligible clinicians in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians.

We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category, and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. While we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For example, when a group of MIPS eligible clinicians chooses to report for MIPS as a group, the data submitted are representative of that entire group, as opposed to each individual MIPS eligible clinician in the group submitting data that exclusively reflect his/her own performance. Approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. Additionally, we are challenged because many of the measures that were available for submission for the 2017 performance period are now unavailable, due to our discontinuation of the Promoting Interoperability transition measure set, and the overhaul of the performance category that further reduced the number of available measures. For these reasons, we are unable to determine, at this time, whether the measures currently specified for the Promoting Interoperability performance category for the 2020 performance period are applicable and available for NPs, PAs, CRNAs, and CNSs. However, as more data beyond this first year become available, we plan to reevaluate the measures and consider how we could ensure that there are sufficient measures applicable and available for these types of MIPS eligible clinicians.

Thus, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2020, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect this proposal. We are requesting public comments on this proposal.

(ii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologist, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2019 PFS final rule (83 FR 59819 through 59820), we adopted a policy at § 414.1380(c)(2)(i)(A)(4) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs for the performance periods in 2017–2019 to these new types of MIPS eligible clinicians (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2019. Because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category.

For the reasons discussed in section III.K.3.c.(4)(f)(i), for the performance period in 2020, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals, and to revise § 414.1380(c)(2)(i)(A)(4) to reflect this proposal. We invite comments on this proposal.

(iii) Hospital-Based MIPS Eligible Clinicians in Groups

We define a hospital-based MIPS eligible clinician under § 414.1305 as a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of services identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital (POS 21), on campus outpatient hospital (POS 22), off campus outpatient hospital (POS 19), or emergency room (POS 23) setting, based on claims for the MIPS determination period (81 FR 77238 through 77240, 82 FR 53686 through 53687, 83 FR 59727 through 59730). We established under § 414.1380(c)(2)(i)(C)(6) that a MIPS eligible clinician who is a hospital-based MIPS eligible clinician as defined in § 414.1305 will be assigned a zero percent weight for the Promoting Interoperability performance category, and the points associated with the Promoting Interoperability performance category will be redistributed to another performance category or categories (81 FR 77238 through 77240, 82 FR 53684, 83 FR 59871). However, if a hospital-based MIPS eligible clinician chooses to report on the Promoting Interoperability performance category measures, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score. We stated that this policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

Under § 414.1310(e)(2)(ii), individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN (81 FR 77058). For groups reporting on the Promoting Interoperability performance category,

we stated that group data should be aggregated for all MIPS eligible clinicians within the group (81 FR 77214 through 77216, 82 FR 53687). We stated that this includes those MIPS eligible clinicians who may qualify for a zero percent weighting of the Promoting Interoperability performance category due to circumstances such as a significant hardship or other type of exception, hospital-based or ASC-based status, or certain types of non-physician practitioners (82 FR 53687). We established at § 414.1380(c)(2)(iii) that for MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting (82 FR 53687, 83 FR 59871). We have heard from several stakeholders that our policy for groups that include hospital-based MIPS eligible clinicians sets a threshold that is too restrictive for a variety of reasons. Some stated that due to high turnover rates for hospital medicine groups, many such groups rely on locum tenens clinicians who may practice in multiple settings. They stated that if a hospital medicine group includes only one MIPS eligible clinician who does not meet the definition of a hospital-based MIPS eligible clinician, it could prevent the group from qualifying for reweighting because not all of the MIPS eligible clinicians in the group would be considered hospital-based. A few acknowledged that while hardship exceptions are available for MIPS eligible clinicians who lack control over CEHRT because they use the hospital's CEHRT, it is an administrative burden to have to submit a hardship exception application, especially if the clinician has a locum tenens relationship. We agree that hospital medicine groups may face unique circumstances due to the nature of their practice area and the staffing practices described by stakeholders. Thus, we are proposing to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We are proposing that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We believe a threshold of more than 75 percent is appropriate because it is consistent with the thresholds for groups in the definitions of facility-based MIPS eligible clinician and non-patient facing MIPS eligible clinician under § 414.1305. We are proposing to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician (or the definition of a non-patient facing MIPS eligible clinician, as proposed in section III.K.3.c.(4)(f)(iv), as defined in § 414.1305.

(iv) Non-Patient Facing MIPS Eligible Clinicians in Groups

We define a non-patient facing MIPS eligible clinician under § 414.1305 as an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician. We established under § 414.1380(c)(2)(i)(C)(5) that a MIPS eligible clinician who is a non-patient facing MIPS eligible clinician as defined in § 414.1305 will be assigned a zero percent weight for the Promoting Interoperability performance category, and the points associated with the Promoting Interoperability performance category will be redistributed to another performance category or categories (81 FR 77240 through 77243, 82 FR 53680–53682, 83 FR 59871). However, if a non-patient facing MIPS eligible clinician chooses to report on the Promoting Interoperability performance category measures, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act regardless of their Promoting Interoperability performance category score. We stated that this policy includes MIPS eligible clinicians choosing to report as part of a group or part of a virtual group (82 FR 53687).

As noted in section III.K.3.c.(4)(f)(iii) of the proposed rule in connection with our discussion of hospital-based MIPS eligible clinicians in groups, under § 414.1380(c)(2)(iii), for MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting. In that section, we are proposing to revise § 414.1380(c)(2)(iii) to account for groups and virtual groups that meet the proposed revised definition of a hospital-based MIPS eligible clinician under § 414.1305, which would only require the group or virtual group to meet a threshold of more than 75 percent instead of a threshold of all of the MIPS eligible clinicians in the group or virtual group. In an effort to more clearly and concisely capture our existing policy for non-patient facing MIPS eligible clinicians, we are proposing to revise § 414.1380(c)(2)(iii) to also account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician under § 414.1305, such that the group or virtual group only has to meet a threshold of more than 75 percent.

(g) Future Direction of the Promoting Interoperability Performance Category

(i) Request for Information (RFI) on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Performance Category

In the past, the Promoting Interoperability performance category measures focused on very general process focused actions supported by health IT. In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62766 through 62768), we sought to expand the potential for Medicare and Medicaid Promoting Interoperability Program measures to include more complex measures and closer relationships to high priority health outcomes.

In this RFI, we are seeking comment on Promoting Interoperability performance category measures that might be relevant to specific clinical priorities or goals related to addressing OUD prevention and treatment. As the Query of PDMP measure matures, we believe it will be essential in improving

prescribing practices. As outlined in section III.K.3.c.(4)(d).(i) of this proposed rule, stakeholders indicated that the Verify Opioid Treatment Agreement measure presented significant implementation challenges for MIPS eligible clinicians. Therefore, we are seeking comment on potential new measures for OUD prevention and treatment that could be included in future years of the Promoting Interoperability performance category. We welcome all comments, but we are seeking comment specifically on possible OUD prevention and treatment measures that include the following characteristics:

- Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;
- Leverage the capabilities of CEHRT where possible, including: near-automatic calculation and reporting of numerator, denominator, exclusions and exceptions to minimize manual documentation required of the provider; and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible;
- Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD–10 or CPT;
- Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider;
- Are applicable to all clinicians (for example, clinicians participating as individuals or as a group, or clinicians located in a rural area, designated health professional shortage area (HPSA), designated medically-underserved area (MUA), or urban area);
- Could potentially align with other MIPS performance categories; and
- Are represented by a measure description, numerator/denominator or yes/no attestation statement, and possible exclusions.

(ii) Request for Information (RFI) on NQF and CDC Opioid Quality Measures

We also are specifically seeking public comment on the development of potential measures for consideration for the Promoting Interoperability performance category that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including the opioid quality measures endorsed by the National Quality Forum (NQF) and the CDC Quality Improvement (QI) opioid measures discussed below. The NQF measures represent a reference point for evaluating opioid prescribing behaviors based on measures that have undergone the rigorous NQF measure endorsement process. The CDC guidelines ''encourage careful and selective use of opioid therapy in the context of managing chronic pain through . . . an evidence-based prescribing guideline.'' [117] The guidelines have led to the development of CDC measures on prescribing practices on which we are seeking comment. We believe these measures may help participants understand the relationship between the measure description and the use of health IT to support the actions of the measures.

For example, the measures may describe a clinical concept, such as the CDC Measure 12: Counsel on Risks and Benefits Annually. The actions for this activity can be supported by CEHRT through the use of standards to record key health information for the patient and to identify which patients should be included in the denominator based on information in the medication list, information gained through medication reconciliation of data received through health information exchange with another health provider of care, and/or information incorporated after a query of a PDMP is completed. The actions for the numerator could include leveraging CEHRT to provide patient-specific education, to capture or record Patient Generated Health Data (PGHD), to engage in secure messaging with the patient and ensure the patient is engaging with their record through a patient portal or an Application Programming Interface (API).

We believe that the clinical actions identified within both the NQF quality measures and the CDC QI opioid measures, can be supported by the standards and functionalities of certified health IT and we welcome public comment on the specific use cases for health IT implementation for the potential measure actions. We recognize that modifications to the NQF and CDC measures may be necessary to make the measures as applicable as possible to all participants of the Promoting Interoperability performance category, and are seeking comment on any modifications that would be necessary. In addition, we note that there is some overlap between some of the NQF quality measures and the CDC QI opioid measures and are seeking comment on whether there are ways in which the two sets of measures could be correlated to support potential new measures of the meaningful use of health IT for the Promoting Interoperability performance category. Finally, we are seeking comment on which measures might best advance the implementation and use of interoperable health IT and encourage information exchange between care teams and with patients.

(A) NQF Quality Measures

Three NQF-endorsed quality measures that were stewarded by the Pharmacy Quality Alliance (PQA) evaluate patients with prescriptions for opioids in combination with benzodiazepines, at high-dosage, or from multiple prescribers and pharmacies. Each measure was evaluated and recommended for endorsement by the NQF's Patient Safety Standing Committee [118] and endorsed by the Consensus Standards Approval Committee. These measures, NQF #2940, #2950, and #2951, were recommended by the NQF Measure Application Partnership for inclusion on the December 2018 Measures Under Consideration List for the Medicare Shared Savings Program.

We are seeking public comment on the development of potential measures for consideration for the Promoting Interoperability performance category that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including the opioid quality measures endorsed by the NQF above and the CDC QI opioid measures discussed below. The NQF measures represent a reference point for evaluating opioid prescribing behaviors based on measures that have undergone the rigorous NQF measure endorsement process. The CDC guidelines ''encourage careful and selective use of opioid therapy in the context of managing chronic pain through . . . an evidence-based prescribing guideline.'' [119] The guidelines have led to the development of CDC measures on prescribing practices on which are seeking comment. We are seeking comment on the following three NQF measures for possible inclusion in the Promoting Interoperability performance category and any modifications that may be

[117] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC–DUIP-QualityImprovementAndCareCoordination-508.pdf.*

[118] *https://www.qualityforum.org/News_And_Resources/Press_Releases/2017/NQF_Statement_on_Endorsement_of_Opioid_Patient_Safety_Measures.aspx.*

[119] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC–DUIP-QualityImprovementAndCareCoordination-508.pdf.*

necessary to maximize their use in the Promoting Interoperability performance category:

- Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940).
- Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950).
- Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951).

We believe these measures relate to activities that hold promise in combatting the opioid epidemic and can be supported using CEHRT to complete the actions of the measures. Therefore, we are seeking comment on how the Promoting Interoperability performance category can incorporate the description of the use of technology into measure guidance if these measures were considered for use by MIPS eligible clinicians. For example, the actions related to the Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950) measure could include using health IT to electronically prescribe the medication, to query a PDMP, to identify other care team members, to conduct medication reconciliation based on information received through health information exchange with other providers of care, and recording key health information in a structured format. Additional information regarding each measure is available using NQF's Quality Positioning System at *http://www.qualityforum.org/QPS/QPSTool.aspx*.

(B) CDC Quality Improvement Opioid Measures

We believe there may be promise in the CDC QI opioid measures based on the prescribing best practices found in Appendix B in the CDC document, ''Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain'' (Implementing the CDC Prescribing Guideline).[120] CDC developed the ''Implementing the CDC Prescribing Guideline'' document to help healthcare providers and systems integrate the CDC Prescribing Guideline [121] and the associated QI opioid measures found in the Implementing the CDC Prescribing Guideline document into their clinical practices. The CDC developed 16 QI opioid measures to align with the recommendations in the CDC Prescribing Guideline and to improve opioid prescribing. These measures are intended to measure implementation of the recommended practices.

Generally, we believe these guidelines and measures are consistent with the objective and measure concept of the Promoting Interoperability performance category where the recommendation in the CDC Prescribing Guideline is the overarching objective and an associated QI opioid measure is a description of the patient population focus (denominator) and the desired action (numerator). The ''Implementing the CDC Prescribing Guideline'' document, also, includes practice-level strategies to help organize and improve the management and coordination of long-term opioid therapy:

- Using an interdisciplinary team approach.
- Establishing practice policies and standards.
- Using EHR data to develop registries and track QI opioid measures.

These following measures address treatment guidelines for initial treatment practices and long-term treatment and outcomes. Examples of measures related to short term OUD prevention and treatment activities include:

- *CDC Measure 2:* Check PDMP Before Prescribing Opioids.
- *CDC Measure 4:* Evaluate Within Four Weeks of Starting Opioids.

Examples of measures related to long term OUD prevention and treatment activities include:

- *CDC Measure 11:* Check PDMP Quarterly.
- *CDC Measure 12:* Counsel On Risks and Benefits Annually.

The data sources from these measures include State PDMP data or the practice EHR data field.

The CDC and the Agency for Healthcare Research and Quality (AHRQ) are also developing electronic clinical decision support tools that can provide real-time clinical decision support for some of the best practices included in the Implementing the CDC Prescribing Guideline document based on well-defined clinical concepts.[122] Well-defined clinical concepts are those that can be discretely represented by available content standards or vocabularies such as SNOMED CT or LOINC. In the context of QI measures, these well-defined clinical concepts that are part of the clinical decision support artifacts, including the clinical conditions or prescribed medications that trigger the decision support, could also be used to develop measures for the Promoting Interoperability performance category related to OUD prevention and treatment. This can create a tight linkage between the guidelines, the recommended clinical actions based on the guidelines, and the improved outcomes based on the recommended clinical actions.

Therefore, we are seeking comment on which of the 16 CDC QI opioid measures have value for potential consideration for the Promoting Interoperability performance category. We are further seeking comment on whether we should consider a different type of measurement concept for OUD prevention and treatment, such as reporting on a set of cross-cutting activities and measures to earn credit in the Promoting Interoperability performance category (for example, a set of one clinical decision support, the related CDC QI opioid measure, and a potentially relevant clinical quality measure). While the CDC quality measures could be implemented for the Quality category, they are highlighted as under consideration for the PI category as they have been linked in the CDC work to the use of CDS artifacts through health IT, as discussed.

We refer readers to the ''Implementing the CDC Prescribing Guideline'' document, and the related measures, in Appendix B of that document, which is available at *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCare Coordination-508.pdf*.

(iii) Request for Information (RFI) on a Metric To Improve Efficiency of Providers Within EHRs

One of the benefits of adopting EHRs is increasing the efficiency of health care processes and generating cost savings by eliminating time-consuming paper-based processes. Through the use of EHRs, health care providers are able to automate administrative aspects of delivery system management, such as coding and scheduling, easily locate patient information in electronic charts, and streamline communications with other health care providers through electronic means.

However, research, also, points to variable results from the implementation of health IT across practice settings, suggesting that health IT adoption is not a universal remedy for inefficient practice. Stakeholders continue to describe ways in which the potential benefits of EHRs have not been fully realized, and are pointing to non-optimized electronic workflows and poor system design that can increase, rather than reduce, administrative burden, which contributes to physician

[120] *https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf*.

[121] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm*.

[122] *https://cds.ahrq.gov/cdsconnect/topic/opioids-and-pain-management*.

burnout.[123] For instance, in many systems, stakeholders have identified EHR functionality associated with clinical documentation, order entry, and messaging as cumbersome. It is our understanding that in order to achieve true EHR efficiency gains in today's healthcare environment, the way forward must include reductions in the persistent sources of technology-related burden, an increased allowance for ancillary medical staff to assist in medical documentation, and through the more effective use of technology.

In November 2018, the Office of the National Coordinator for Health Information Technology (ONC) released the draft report ''Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs,'' [124] as required by section 4001 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). In the draft report, ONC described a variety of factors that may contribute to EHR-related burden, and provided draft recommendations for how HHS, as well as other stakeholders may be able to address these factors. Specifically, the draft report discussed processes where adoption of improved electronic processes could reduce the EHR-related burden, such as processes related to prior authorization requests. The draft report, also, discussed EHR usability and design challenges which may contribute to EHR-related burden, and identified best practices for design, as well as a variety of emerging system features which may improve efficiency in health IT usage. We believe further adoption of more efficient workflows and technologies, such as those identified in the draft report, will help health care providers with overall improvements in patient care and interoperability, and we are seeking comment on how such implementation of such processes can be effectively measured and encouraged as part of the Promoting Interoperability performance category.

We also are interested in how to measure and incentivize efficiency as it relates to the meaningful use of CEHRT and the furthering of interoperability. In 2017, the NQF released, ''A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy,'' [125] which included discussion of measure concepts of productivity and efficiency that can result from the use of health IT, specifically the health information exchange. For instance, the NQF report identifies a measure concept for the ''percentage of reduction of duplicate labs and imaging over time,'' which can capture the impact of electronic availability of imaging studies on duplicative studies that are often conducted when health care providers do not have the ability to locate an existing study. However, we recognize that there are challenges associated with tying such measures of economic efficiency to a single factor, such as electronic workflow improvements.[126]

Consistent with our commitment to reducing administrative burden, increasing efficiencies, and improving beneficiary experience via the ''Patients over Paperwork initiative,'' [127] we are seeking stakeholder feedback on a potential metric to evaluate health care provider efficiency using EHRs. Specifically, we are requesting information on the following questions:

- What do stakeholders believe would be useful ways to measure the efficiency of health care processes due to the use of health IT? What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or yes/no reporting, and exclusions.
- What do stakeholders believe may be hindering their ability to achieve greater efficiency (for example, product, measures, CMS regulations)? Please, provide examples.
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability performance category) that can increase the efficiency of provider interactions with technology systems; for instance, alternate authentication technologies that can simplify provider logon? How could we reward providers for adoption and use of these technologies?
- What are key administrative processes that can benefit from more efficient electronic workflows; for instance, conducting prior authorization requests? How can we measure and reward providers for their uptake of more efficient electronic workflows?
- Could CMS successfully incentivize efficiency? What role should CMS play in improving efficiency in the practice of medicine? The underlying goal is to move to a more streamlined, efficient, easier user experience, whereby providers can input and access a patient's data in a reliable, timely manner. Having not yet reached this point, we are seeking feedback on the best way(s) to get there.

(iv) Request for Information (RFI) on the Provider to Patient Exchange Objective

In March 2018, the White House Office of American Innovation and the CMS Administrator announced the launch of MyHealthEData and CMS' role in improving patient access and advancing interoperability. As part of the MyHealthEData initiative, we are taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their computable health information and can be assured that their health information will follow them as they move throughout the health care system from provider to provider, payer to payer. To accomplish this, we have launched several initiatives related to data sharing and interoperability to empower patients and encourage plan and provider competition. One example is our overhaul of the Advancing Care Information performance category under MIPS to transform it into the new Promoting Interoperability performance category, which put a heavy emphasis on patient access to their health information through the Provide Patients Electronic Access to Their Health Information measure.

Through the Provide Patients Electronic Access to Their Health Information measure, we are ensuring that patients have access to their information through any application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT. To make these APIs fully useful to patients, they should provide immediate access to updated information whenever the patient needs that information, should be always available, configured using standardized technology and contain the information a patient needs to make informed decisions about their care.

In the CY 2019 PFS proposed rule (83 FR 35932), we introduced a potential future Promoting Interoperability performance category concept that explored creating a set of priority health IT activities that would serve as alternatives to the traditional Promoting

[123] *https://www.ahrq.gov/professionals/clinicians-providers/ahrq-works/burnout/index.html.*

[124] *https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.*

[125] *https://www.qualityforum.org/Publications/2017/09/Interoperability_2016-2017_Final_Report.aspx.*

[126] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699907/.*

[127] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html.*

Interoperability performance category measures. We requested public comment on whether MIPS eligible clinicians should earn credit in the Promoting Interoperability performance category by attesting to health IT or interoperability activities in lieu of reporting on specific measures. We identified specific health IT activities and sought public comment on those and additional activities that would add value for patients and health care providers, are relevant to patient care and clinical workflows, support alignment with existing objectives, promote flexibility, are feasible for implementation, are innovative in the use of health IT, and promote interoperability. We received feedback in support of this future concept.

One such activity that we specifically requested comment on was a health IT activity in which MIPS eligible clinicians may obtain credit in the Promoting Interoperability performance category if they maintain an ''open API,'' or standards-based API, which allows patients to access their health information through a preferred third-party application. An API can be thought of as a set of commands, functions, protocols, or tools published by one software developer (''Developer A'') that enables other software developers to create programs (applications or ''apps'') that can interact with developer A's software without needing to know the internal workings of developer A's software, all while maintaining consumer privacy data standards. This is how API technology creates a seamless user experience that is, typically, associated with other applications that are used in more common aspects of consumers' daily lives, such as travel and personal finance. Standardized, transparent, and pro-competitive API technology can enable similar benefits to consumers of health care services.[128]

We received feedback from several commenters regarding concerns that an ''open'' API may open the door to patient data without security, leaving MIPS eligible clinicians' EHR systems open for cyber-attacks. However, we wish to note that the term ''open API'' does not imply that any and all applications or application developers would have unfettered access to individuals' personal or sensitive information nor would it allow for any reduction in the required protections for privacy and security of patient health information. Additionally, with respect to patient access, a patient will need to authenticate him/herself to a health care organization that is the steward of their data (for example, username and password) and the access provided to an app will be for that one patient. The overall HIPAA Security Rule, HIPAA Privacy Rule, and other cybersecurity obligations that apply to HIPAA covered entities remain the same and would need to be applied to an API in the same way they are currently applied to any and all other interfaces a health care organization deploys in production.

ONC's 21st Century Cures Act proposed rule (84 FR 7424 through 7610) includes new proposals that focus on how certified health IT can use APIs to allow health information to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law. For instance, ONC has proposed to adopt a new criterion for a standards-based API at § 170.315(g)(10). This standards-based API criterion would replace the existing API criterion with one that requires the use of the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard. ONC has also proposed a series of requirements for the standards-based API that would improve interoperability by focusing on standardized, transparent, and pro-competitive API practices.

ONC has proposed to make the standards-based API criterion part of the 2015 Edition base EHR definition (84 FR 7427), which would ensure that this functionality is ultimately included in the CEHRT definition required for participation in the Promoting Interoperability performance category. If finalized, health IT developers would have 24 months from the publication of the final rule to implement these changes to certified health IT products.

(A) Immediate Access

The existing Provide Patients Electronic Access to Their Health Information measure specifies that the MIPS eligible clinicians provide the patient timely access to view online, download, and transmit his or her health information, and further specifies that patient health information must be made available to the patient within 4 business days of its availability to the MIPS eligible clinicians. We believe it is critical for patients to have access to their health information when making decisions about their care. In the recently published proposed rule titled, ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers proposed rule'' (84 FR 7610 through 7680) (hereinafter referred to as the ''CMS Interoperability and Patient Access proposed rule''), we proposed that certain health plans and payers be required to make patient health information available through an open, standards-based API no later than one business day after it is received by the health plan or payer.

Recognizing the importance of patients having access to their complete health information, including clinical information from the MIPS eligible clinicians' CEHRT, and appreciating the new technical flexibility a standards-based API would provide, we are seeking comment on whether MIPS eligible clinicians should make patient health information available immediately through an open, standards-based API, no later than one business day after it is available to the MIPS eligible clinicians in their CEHRT. We seek comment on the barriers to more immediate access to patient information. Additionally, we seek comment on whether there are specific data elements that may be more or less feasible to share no later than one business day. We also seek comment as to when implementation of such a requirement is feasible.

(B) Persistent Access and Standards-Based APIs

As discussed above, the ONC 21st Century Cures Act proposed rule (84 FR 7479) includes a proposal for adoption of API conditions of certification that ensure a standards-based API is implemented in a manner that provides unimpeded access to technical documentation, is non-discriminatory, preserves rights of access, and minimizes costs or other burdens that could result in special effort. The ONC 21st Century Cures Act proposed rule (84 FR 7575), also, includes requirements for the standardized API related to privacy and security to ensure that patient health information is protected.

The existing Provide Patients Electronic Access to Their Health Information measure does not specify the overall operational expectations associated with enabling patients' access to their health information. For instance, the measure only specifies that

[128] ONC has made available a succinct, non-technical overview of APIs in context of consumers' access to their own medical information across multiple providers' EHR systems, which is available at the *HealthIT.gov* website at *https://www.healthit.gov/api-education-module/story_html5.html*.

access must be ''timely.'' As a result, we request public comment on whether we should revise the measure to be more specific with respect to the experience patients should have regarding their access. For instance, in the ONC 21st Century Cures Act proposed rule (84 FR 7481 through 7484), there is a proposal regarding requirements around persistent access to APIs, which would accommodate a patient's routine access to their health information without needing to reauthorize their application and re-authenticate themselves. We seek comment on whether the Promoting Interoperability performance category measure should be updated to accommodate this proposed technical requirement for persistent access.

As we work to advance interoperability and empower patients through access to their health information, we continue to explore the role of APIs. We support the ONC 21st Century Cures Act proposed rule (84 FR 7424) proposal to move to an HL7 FHIR®-based API under 2015 Edition certification (84 FR 7479). Health care providers committed to a standards-based API could benefit from joining in on the industry's new FHIR standards framework to reduce burden in, and improve on, quality measurement through automation and simplification. Use of FHIR-based APIs could help push forward interoperability regardless of EHR systems used providing standardized way to share information.

Understanding this, we are, specifically, seeking public comments on the following question:

- If ONC's proposed FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability performance category for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs?

(C) Available Data

Recognizing the overall burden that switching EHR systems places on health care providers, ONC has introduced a new proposal that seeks to minimize that burden. In the ONC 21st Century Cures Act proposed rule, ONC proposed to adopt a new 2015 Edition certification criterion for the EHI export at 45 CFR 170.315(b)(10). The purpose of this criterion is to provide patients and health IT users the ability to securely export the entire EHR for a single patient, or all patients, in a computable, electronic format, and facilitate receiving the health IT system's interpretation, and use of the EHI, to the extent that is reasonably practicable using the existing technology of developers. This patient-focused export capability complements other provisions of the proposed rule that support patients' access to their EHI, including information that may eventually be accessible via the proposed standardized API in 45 CFR 170.215. It is also complementary to the proposals in the CMS Interoperability and Patient Access proposed rule, which proposed to require certain health plans and issuers to provide patients access to their health data through a standardized API.

Building on these proposals, we are seeking comment on an alternative measure under the Provider to Patient Exchange objective that would require clinicians to use technology certified to the EHI criterion to provide the patient(s) their complete electronic health data contained within an EHR.

Specifically, we are seeking comment on the following questions:

- Do stakeholders believe that incorporating this alternative measure into the Provider to Patient Exchange objective will be effective in encouraging the availability of all data stored in health IT systems?
- In relation to the Provider to Patient Exchange objective, as a whole, how should a required measure focused on using the proposed total EHI export function in CEHRT be scored?
- If this certification criterion is finalized and implemented, should a measure based on the criterion be established as a bonus measure? Should this measure be established as an attestation measure?
- In the long term, how do stakeholders believe such an alternative measure would impact burden?
- If stakeholders do not believe this will have a positive impact on burden, in what other way(s) might an alternative measure be implemented that may result in burden reduction? Please, be specific.
- Which data elements do stakeholders believe are of greatest clinical value or would be of most use to health care providers to share in a standardized electronic format if the complete record was not immediately available?

In addition to the above questions, we have some general questions that are related to health IT activities, for which we are, also, seeking public comment:

- Do stakeholders believe that we should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bi-directional exchange of health information with community partners, such as post-acute care, long-term care, behavioral health, and home and community based services to promote better care coordination for patients with chronic conditions and complex care needs? If so, what criteria should we consider when implementing a health information exchange across the care continuum health IT activity in the Promoting Interoperability performance category?
- What criteria should we employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the performance category?
- Are there additional health IT activities we should consider recognizing in lieu of reporting on existing measures and objectives that would most effectively advance priorities for nationwide interoperability and spur innovation?

(D) Patient Matching

ONC has stated that patient matching is critically important to interoperability and the nation's health IT infrastructure as health care providers must be able to share patient health information and accurately match a patient to his or her data from a different health care provider in order for many anticipated interoperability benefits to be realized. We continue to support ONC's work promoting the development of patient matching initiatives. Per Congress' guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a unique patient identifier (UPI). We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard (84 FR 7656).

Recognizing Congress' statement regarding patient matching and stakeholder comments stating that a patient matching solution would accomplish the goals of a UPI, we are seeking comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We are also seeking comment on how we may leverage our authority to provide support to those working to improve patient matching. We note that we intend to use comments we receive for

the development of policy and future rulemaking.

- Do stakeholders believe that CMS and ONC patient matching efforts impact burden? Please, explain.
- If stakeholders believe that patient matching is leading to increased burden, what suggestions might stakeholders have to promote interoperability securely and accurately, without the requirement of a UPI, that may result in burden reduction? Please, be specific.

(v) Request for Information (RFI) on Integration of Patient-Generated Health Data Into EHRs Using CEHRT

The Promoting Interoperability performance category is continuously seeking ways to prioritize the advanced use of CEHRT functionalities, encourage movement away from paper-based processes that increase health care provider burden, and empower individual beneficiaries to take a more impactful role in managing their health to achieve their goals. Increased availability of patient-generated health data (PGHD) [129] offers providers an opportunity to monitor and track a patient's health-related data from information that is provided by the patient and not the provider. Increasingly affordable wearable devices, sensors, and other technologies capture PGHD, providing new ways to monitor and track a patient's healthcare experience. Capturing important health information through devices and other tools between medical visits could help improve care management and patient outcomes, potentially resulting in increased cost savings. Although many types of PGHD are being used in clinical settings today, the continuous collection and integration of patients' health-data into EHRs to inform clinical care has not been widely achieved across the health care system.

In the 2015 Edition Health IT Certification Criteria final rule (80 FR 62661; 45 CFR 170.315(e)(3)), ONC finalized a criterion for patient health information capture functionality within certified health IT that allows a user to identify, record, and access information directly and electronically shared by a patient. We finalized a PGHD measure requiring health care providers to incorporate PGHD or data from a nonclinical setting into CEHRT (80 FR 62851). However, we removed this measure in the CY 2019 PFS final rule (83 FR 59813), due to concerns that the measure was not fully health IT-based and could include paper-based actions, an approach which did not align with program priorities to advance the use of CEHRT. Stakeholder comments regarding this measure also noted that manual processes to conduct actions associated with the measure could increase health care provider reporting burden and that there was confusion over which types of data would be applicable and the situations in which the patient data would apply. At the same time, there was ample support from the public for ONC and CMS to continue to advance certified health IT capabilities to capture PGHD.

However, we continue to believe that it is important for the Promoting Interoperability performance category to explore new ways to incentivize health care providers who take proactive steps to advance the emerging use of PGHD. As relevant technologies and standards continue to evolve, there may be new approaches through which we can address challenges related to emerging standards for PGHD capture, appropriate clinical workflows for receiving and reviewing PGHD, and advance the technical architecture needed to support PGHD use.

In 2018, ONC released the white paper, ''Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024,'' [130] which described key challenges, opportunities and enabling actions for different stakeholders, including clinicians, to advance the use of PGHD. For instance, the report identified an enabling action around supporting ''clinicians to work within and across organizations to incorporate prioritized PGHD use cases into their workflows.'' This action urges clinicians and care teams to identify priority use cases and relevant PGHD types that would be valuable to improving care delivery for patient populations. It, also, highlights the importance of developing clinical workflows that avoid overwhelming the care team with extraneous data by encouraging care teams to develop management strategies for shared responsibilities around collecting, verifying, and analyzing PGHD. A second enabling action the white paper identifies for clinicians is, ''collaboration between clinicians and developers to advance technologies supporting PGHD interpretation and use.'' This enabling action highlights feedback for developers about prioritized use cases and application features as critical to ensuring that the necessary refinements are made to technology solutions to effectively support the capture and use of PGHD. Finally, the report encourages ''clinicians in providing patient education to encourage PGHD capture and use in ways that maximize data quality,'' recognizing the important role that clinicians can play in helping patients understand how to share PGHD, the differences between solicited and unsolicited PGHD, and how PGHD are relevant for the patient's care.

Considering the enabling actions for clinicians identified in the white paper, we are interested in ways that the Promoting Interoperability performance category could adopt new elements related to PGHD that: (1) Represent clearly defined uses of health IT; (2) are linked to positive outcomes for patients; and (3) advance the capture, use, and sharing of PGHD. In considering how the Promoting Interoperability performance category could continue to advance the use of PGHD, we also note that a future element related to PGHD would not necessarily need to be implemented as a traditional measure requiring reporting of a numerator and denominator. For instance, in the CY 2019 PFS proposed rule (83 FR 35932), we requested comment on the concept of ''health IT'' or ''interoperability'' activities to which a health care provider could attest, potentially in lieu of reporting on measures associated with certain objectives. By addressing the use of PGHD through such a concept, rather than traditional measure reporting, we could potentially reduce the reporting burden associated with a new PGHD-related element.

We are inviting stakeholder comment on these concepts, and the specific questions below:

- What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.
- Should the Promoting Interoperability performance category explore ways to reward providers for engaging in activities that pilot promising technical solutions or approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?
- Should health care providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?
- Should the Promoting Interoperability performance category

[129] For more information, we refer readers to *https://www.healthit.gov/topic/scientific-initiatives/patient-generated-health-data.*

[130] *https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf.*

explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?

We believe the bi-directional availability of data, meaning that both patients and their health care providers have real-time access to the patient's electronic health record, is critical. This includes patients being able to import their health data into their medical record and have it be available to health care providers. We welcome input on how we can encourage, enable, and reward health care providers to advance capture, exchange, and use of PGHD.

(vi) Request for Information (RFI) on Engaging in Activities That Promote the Safety of the EHR

The widespread adoption of EHRs has transformed the way health care is delivered, offering improved availability of patient health information, supporting more informed clinical decision making, and reduce medical errors.[131] However, many stakeholders have identified risks to patient safety as one of the unintended consequences that may result from the implementation of EHRs. By disrupting established workflows and presenting clinicians with new challenges, EHR implementation may increase the incidence of certain errors, resulting in harm to patients.

As we continue to advance the use of CEHRT in health care, we are seeking comment on how to further mitigate the specific safety risks that may arise from technology implementation. Specifically, we are seeking comment on ways that the Promoting Interoperability performance category may reward MIPS eligible clinicians for engaging in activities that can help to reduce the errors associated with EHR implementation.

For instance, we are requesting comment on a potential future change to the performance category under which MIPS eligible clinicians would receive points towards their Promoting Interoperability performance category score for attesting to performance of an assessment based on one of the ONC SAFER Guides. The SAFER Guides (available at *https://www.healthit.gov/topic/safety/safer-guides*) are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of EHRs in nine different areas: High Priority Practices, Organizational Responsibilities, Contingency Planning, System Configuration, System Interfaces, Patient Identification, Computerized Provider Order Entry, Test Results Reporting and Follow-Up, and Clinician Communication.

Each of the SAFER Guides is based on the best evidence available, including a literature review, expert opinion, and field testing at a wide range of healthcare organizations, from small ambulatory practices to large health systems. A number of EHR developers currently utilize the SAFER Guides as part of their health care provider training modules.

Specifically, we might consider offering points towards the Promoting Interoperability performance category score to MIPS eligible clinicians that attest to conducting an assessment based on the High Priority Practices [132] and/or the Organizational Responsibilities [133] SAFER Guides which cover many foundational concepts from across the guides. Alternatively we might consider awarding points for review of all nine of the SAFER Guides. We are also inviting comments on alternatives to the SAFER Guides, including appropriate assessments related to patient safety, which should also be considered as part of any future bonus option.

We are requesting comment on the ideas above, as well as inviting stakeholders to suggest other approaches we may take to rewarding activities that promote reduction of safety risks associated with EHR implementation as part of the Promoting Interoperability performance category.

(5) APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

As codified at § 414.1370(a), the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the of an APM Entity participating in a MIPS APM for the applicable MIPS performance period.

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), the APM scoring standard is designed to reduce reporting burden for such clinicians by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and MIPS.

We established at § 414.1370(c) that the MIPS performance period under § 414.1320 applies for the APM scoring standard. We finalized under § 414.1370(f) that the MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity, and the MIPS payment adjustment is applied at the TIN/NPI level for each MIPS eligible clinician in the APM Entity group. Under § 414.1370(f)(2), if the APM Entity group is excluded from MIPS, all eligible clinicians within that APM Entity group are also excluded from MIPS.

As finalized at § 414.1370(h)(1) through (4), the performance category weights used to calculate the MIPS final score for an APM Entity group for the APM scoring standard performance period are: Quality at 50 percent; cost at 0 percent; improvement activities at 20 percent; and Promoting Interoperability at 30 percent.

(b) MIPS APM Criteria

We established at § 414.1370(b) that for an APM to be considered a MIPS APM, it must satisfy the following criteria: (1) APM Entities must participate in the APM under an agreement with CMS or by law or regulation; (2) the APM must require that APM Entities include at least one MIPS eligible clinician on a Participation List; (3) the APM must base payment on quality measures and cost/utilization; and (4) the APM must be neither a new APM for which the first performance period begins after the first day of the MIPS performance year nor an APM in the final year of operation for which the APM scoring standard is impracticable. In the CY 2019 PFS final rule (59820 through 59821), we clarified that we consider whether each distinct track of an APM meets the criteria to be a MIPS APM and that it is possible for an APM to have tracks that are MIPS APMs and tracks that are not MIPS APMs. We also clarified that we consider the first performance year for an APM to begin as of the first date for which eligible clinicians and APM entities participating in the model must report on quality measures under the terms of the APM.

Based on the MIPS APM criteria, we expect that the following 10 APMs will satisfy the requirements to be MIPS APMs for the 2020 MIPS performance period:

- Comprehensive ESRD Care Model (all Tracks).
- Comprehensive Primary Care Plus Model (all Tracks).
- Next Generation ACO Model.
- Oncology Care Model (all Tracks).

[131] *https://www.healthit.gov/topic/health-it-basics/improved-patient-care-using-ehrs.*

[132] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

[133] *https://www.healthit.gov/sites/default/files/safer/guides/safer_organizational_responsibilities.pdf.*

- Medicare Shared Savings Program (all Tracks).
- Medicare ACO Track 1+ Model.
- Bundled Payments for Care Improvement Advanced.
- Maryland Total Cost of Care Model (Maryland Primary Care Program).
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).
- Primary Care First (All Tracks).

Final CMS determinations of MIPS APMs for the 2020 MIPS performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. Further, we make these determinations based on the established MIPS APM criteria as specified in § 414.1370(b).

(c) Calculating MIPS APM Performance Category Scores

(i) Quality Performance Category

As noted, the APM scoring standard is designed to reduce reporting burden for MIPS eligible clinicians participating in MIPS APMs by reducing the need for duplicative data submission to MIPS and their respective APMs, and to avoid potentially conflicting incentives between those APMs and MIPS. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), due to operational constraints, we did not require MIPS eligible clinicians participating in MIPS APMs other than the Shared Savings Program and the Next Generation ACO Model to submit data on quality measures for purposes of MIPS for the 2017 MIPS performance period. As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53695), we designed a means of overcoming these operational constraints and required MIPS eligible clinicians participating in such MIPS APMs to submit data on APM quality measures for purposes of MIPS beginning with the 2018 MIPS performance period. We also finalized a policy to reweight the quality performance category to zero percent in cases where an APM has no measures available to score for the quality performance category for a MIPS performance period, such as where none of the APM's measures would be available for calculating a quality performance category score by the close of the MIPS submission period because measures were removed from the APM measure set due to changes in clinical practice guidelines. Although we anticipated different scenarios where quality would need to be reweighted, we did not anticipate at that time that the quality performance category would need to be reweighted regularly.

After several years of implementation of the APM scoring standard, we have found that for participants in certain MIPS APMs (as defined in § 414.1305), it often is not operationally possible to collect and score performance data on APM quality measures for purposes of MIPS because these APMs run on episodic or yearly timelines that do not always align with the MIPS performance periods and deadlines for data submission, scoring, and performance feedback. In addition, although we anticipated different scenarios where quality would need to be reweighted, we do not believe the quality performance category should be reweighted regularly.

To achieve the aims of the APM scoring standard, we believe it is necessary to consider new approaches to quality performance category scoring.

(A) Allowing MIPS Eligible Clinicians Participating in MIPS APMs To Report on MIPS Quality Measures

We propose to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS quality performance category beginning with the 2020 MIPS performance period.

Similar to our approach for the Promoting Interoperability performance category, we would allow MIPS eligible clinicians in MIPS APMs to receive a score for the quality performance category either through individual or TIN-level reporting based on the generally applicable MIPS reporting and scoring rules for the quality performance category. Under such an approach, we would attribute one quality score to each MIPS eligible clinician in an APM Entity by looking at both individual and TIN-level data submitted for the eligible clinician and using the highest reported score, excepting scores reported by a virtual group. Thus, we would use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

As with Promoting Interoperability performance category scoring, each MIPS eligible clinician in the APM Entity group would receive one score, weighted equally with that of the other MIPS eligible clinicians in the APM Entity group, and we would calculate one quality performance category score for the entire APM Entity group. If a MIPS eligible clinician has no quality performance category score—if the individual's TIN did not report and the individual did not report—that MIPS eligible clinician would contribute a score of zero to the aggregate APM Entity group score.

We would use only scores reported by an individual MIPS eligible clinician or a TIN reporting as a group; we would not accept virtual group level reporting because a virtual group level score is too far removed from the eligible clinician's performance on quality measures for purposes of the APM scoring standard.

We request comment on this proposal.

(B) APM Quality Reporting Credit

We are also proposing to apply a minimum score of 50 percent, or an ''APM Quality Reporting Credit'' under the MIPS quality performance category for certain APM entities participating in MIPS, where APM quality data cannot be used for MIPS purposes as outlined below. Several provisions of the statute address the possibility of considerable overlap between the requirements of MIPS and those of an APM. Most notably, section 1848(q)(1)(C)(ii) of the Act excludes QPs and partial QPs that do not elect to participate in MIPS from the definition of a MIPS eligible clinician. In addition, section 1848(q)(5)(C)(ii) of the Act requires that participation by a MIPS eligible clinician in an APM (as defined in section 1833(z)(3)(C) of the Act) earn such MIPS eligible clinician a minimum score of one-half of the highest potential score for the improvement activities performance category.

In particular, we believe that section 1848(q)(5)(C)(ii) of the Act reflects an understanding that APM participation requires significant investment in improving clinical practice, which may be duplicative with the requirements under the improvement activities performance category. We believe that MIPS APMs require an equal or greater investment in quality, which, due to operational constraints, cannot always be reflected in a MIPS quality performance category score. Accordingly, we are proposing to apply a similar approach to quality performance category scoring under the APM scoring standard. Specifically, we are proposing that APM Entity groups participating in MIPS APMs receive a minimum score of one-half of the highest potential score for the quality performance category, beginning with the 2020 MIPS performance period.

To the extent possible, we would calculate the final score by adding to the credit any additional MIPS quality score received on behalf of the individual NPI or the TIN. For the purposes of final

scoring this credit would be added to any MIPS quality measure scores we receive. All quality category scores would be capped at 100 percent. For example, if the additional MIPS quality score were 40 percent, that would be added to the 50 percent credit for a total of 90 percent; if the quality score were 70 percent, that would be added to the 50 percent credit and because the result is 120 percent, the cap would be applied for a final score of 100 percent.

We request comment on this proposal.

(i) Exceptions From APM Quality Reporting Credit

Under this proposal, we would not apply the APM Quality Reporting Credit to the APM Entity group's quality performance score for those APM Entities reporting only through a MIPS quality reporting mechanism according to the requirements of their APM, such as the Medicare Shared Savings Program, which requires participating ACOs to report through the CMS Web Interface and the CAHPS for ACOs survey measures. In these cases, no burden of duplicative reporting would exist, and there would not be any additional unscored quality measures for which to give credit.

In the case where an APM Entity group is in an APM that requires reporting through a MIPS quality reporting mechanism under the terms of participation in the APM, should the APM Entity group fail to report on required quality measures, the individual eligible clinicians and TINs that make up that APM Entity group would still have the opportunity to report quality measures to MIPS for purposes of calculating a MIPS quality performance category score as finalized in they would in any Other MIPS APM in accordance with § 414.1370(g)(1)(ii). However, as in these cases no burden of duplicative reporting would exist, they would remain ineligible for the APM Quality Reporting credit.

(C) Additional Reporting Option for APM Entities

We recognize that some APM Entities may have a particular interest in ensuring that MIPS eligible clinicians in the APM Entity group perform well in MIPS, or in reducing the overall burden of joining the entity. Likewise, we recognize that some APMs, such as the CMS Web Interface reporters already require reporting on MIPS quality measures as part of participation in the APM. Therefore, we are proposing that, in instances where an APM Entity has reported quality measures to MIPS through a MIPS submission type and using MIPS collection type on behalf of the APM Entity group, we would use that quality data to calculate an APM Entity group level score for the quality performance category. We believe this approach best ensures that all participants in an APM Entity group receive the same final MIPS score while reducing reporting burden to the greatest extent possible.

We request comment on this proposal.

(D) Bonus Points and Caps for the Quality Performance Category

In the 2018 Quality Payment Program final rule (82 FR 53568, 53700), we finalized our policies to include bonus points in the performance category score calculation when scoring quality at the APM Entity group level. Because these adjustments would, under the proposals discussed in section[s] III.J.3.d.(1)(b) of this proposed rule, already be factored in when calculating an individual or TIN-level quality performance category score before the quality scores are rolled-up and averaged to create the APM Entity group level score, we believe it would be inappropriate to continue to calculate these adjustments at the APM Entity group level in the case where an APM Entity group's quality performance score is reported by its composite individuals or TINs. However, in the case of an APM Entity group that chooses to or is required by its APM to report on MIPS quality measures at the APM Entity group level, we would continue to apply any bonuses or adjustments that are available to MIPS groups for the measures reported by the APM Entity and to calculate the applicability of these adjustments at the APM Entity group level.

We request comment on this proposal.

(E) Special Circumstances

In prior rulemaking, with regard to the quality performance category, we did not include MIPS eligible clinicians who are subject to the APM scoring standard in the automatic extreme and uncontrollable circumstances policy or the application-based extreme and uncontrollable circumstances policy that we established for other MIPS eligible clinicians (82 FR 53780–53783, 53895–53900; 83 FR 59874–59875). However, in section III.J.3.c.(5)(c)(i)(c) of this proposed rule, we are proposing to allow MIPS eligible clinicians participating in MIPS APMs to report on MIPS quality measures and be scored for the MIPS quality performance category based on the generally applicable MIPS reporting and scoring rules for the quality performance category. In light of this proposal, we believe that the same extreme and uncontrollable circumstances policies that apply to other MIPS eligible clinicians with regard to the quality performance category should also apply to MIPS eligible clinicians participating in MIPS APMs who would report on MIPS quality measures as proposed. Therefore, beginning with the 2020 MIPS performance period/2022 MIPS payment year and only with regard to the quality performance category, we propose to apply the application-based extreme and uncontrollable circumstances policy (82 FR 53780–53783) and the automatic extreme and uncontrollable circumstances policy (83 FR 59874–59875) that we previously established for other MIPS eligible clinicians and codified at § 414.1380(c)(2)(i)(A)(6) and (8), respectively, to MIPS eligible clinicians participating in MIPS APMs who are subject to the APM scoring standard and would report on MIPS quality measures as proposed in section III.J.3.c.(5)(c)(i). We would limit the proposed application of these policies to the quality performance category because our proposal in section III.J.3.c.(5)(c)(i) pertains to reporting on MIPS quality measures.

Under the previously established policies, MIPS eligible clinicians who are subject to extreme and uncontrollable circumstances may receive a zero percent weighting for the quality performance category in the final score (82 FR 53780–53783, 83 FR 59874–59875). Similar to the policy for MIPS eligible clinicians who qualify for a zero percent weighting of the Promoting Interoperability performance category (82 FR 53701 through 53702), we propose that if a MIPS eligible clinician who qualifies for a zero percent weighting of the quality performance category in the final score is part of a TIN reporting at the TIN level that includes one or more MIPS eligible clinicians who do not qualify for a zero percent weighting, we would not apply the zero percent weighting to the qualifying MIPS eligible clinician. The TIN would still report on behalf of the entire group, although the TIN would not need to report data for the qualifying MIPS eligible clinician. All MIPS eligible clinicians in the TIN who are participants in the MIPS APM would count towards the TIN's weight when calculating the aggregated APM Entity score for the quality performance category.

However, in this circumstance, if the MIPS eligible clinician was a solo practitioner and qualified for a zero percent weighting, if the MIPS eligible clinician's TIN did not report at the group level and the MIPS eligible

clinician was individually eligible for a zero percent weighting, or if all MIPS eligible clinicians in a TIN qualified for the zero percent weighting, neither the TIN nor the individual would be required to report on the quality performance category and would be assigned a weight of zero when calculating the APM Entity's quality performance category score.

If quality performance data were reported by or on behalf of one or more TIN/NPIs in an APM Entity group, a quality performance category score would be calculated for, and would be applied to, all MIPS eligible clinicians in the APM Entity group. If all MIPS eligible clinicians in all TINs of an APM Entity group qualify for a zero percent weighting of the quality performance category, the quality performance category would be weighted at zero percent of the MIPS final score.

We welcome comments from the public in this discussion of how best to address the technical infeasibility of scoring quality for many of our MIPS APMs, and whether the above described policy or some other approach may be an appropriate path forward for the APM entity group scoring standard in CY 2020.

We request comment on this proposal.

(d) Request for Comment on APM Scoring Beyond 2020

We are also seeking comment on potential policies to be included in next year's rulemaking to further address the changing incentives for APM participation under MACRA. We want the design of the APM scoring standard to continue to encourage appropriate shifts of MIPS eligible clinicians into MIPS APMs and eventually into Advanced APMs while ensuring fair treatment for all MIPS eligible clinicians.

We note that the QP threshold will be increasing in future years, potentially resulting in larger proportions of Advanced APM participants being subject to MIPS under the APM scoring standard. At the same time the MIPS performance threshold will be increasing annually, gradually reducing the impact of the APM scoring standard on participants' ability to achieve a neutral or positive payment adjustment under MIPS.

(F) Excluding Virtual Groups From APM Entity Group Scoring

Due to concerns that virtual groups could be used to calculate APM Entity group scores, we have excluded virtual group MIPS scores when calculating APM Entity group scores. Previously, we have effectuated this exclusion through the use and application of terms defined in § 414.1305, specifically, ''APM Entity,'' ''APM Entity group,'' ''group,'' and ''virtual group.'' To improve clarity around the exclusion of virtual group scores in calculating APM Entity group scores, we now are proposing to effectuate this exclusion more explicitly, by amending § 414.1370(e)(2) to state that the score calculated for an APM Entity group, and subsequently the APM Entity, for purposes of the APM scoring standard does not include MIPS scores for virtual groups.

(i) Sunsetting the APM Quality Reporting Credit for APM Entities

One proposal we may consider beginning in the 2021 performance year would be to apply the APM Quality Reporting Credit described above, if finalized, to specific APM Entities for a maximum number of MIPS performance years; this may be set for all APMs or tied to the end of each APM's initial agreement period.

We believe that this proposal would create an incentive for new APM Entity groups to continue to form and join new MIPS APMs while maintaining the incentive for APM Entity groups and MIPS eligible clinicians to continue to strive to achieve QP status. This proposal also would complement the shift we are seeing within APMs, such as the Shared Savings Program, to require APM participants to move into two-sided risk tracks and Advanced APMs within 2 to 5 years of joining the model or program.

(ii) Sunsetting the APM Quality Reporting Credit for Non-Advanced APMs

Similar to the first proposal, we may consider an approach whereby we would implement the above approach to quality scoring and then phase out the APM Quality Reporting Credit for MIPS APMs that are not also Advanced APM tracks.

We would have the option to implement this change by removing the APM Reporting Credit for non-Advanced MIPS APMs entirely at the end of a set number of years for all non-Advanced APMs (for example, 2 years).

Alternatively we could tie this sunsetting of the APM Quality Reporting Credit for a non-Advanced APM to the initial agreement period of each APM, creating a well-timed incentive for movement into Advanced APM tracks of an APM after the initial agreement period after the start of the APM.

(iii) Sunsetting the APM Quality Reporting Credit for APM Entities in One-Sided Risk Tracks

One possible way of acknowledging the uncertainty involved with joining an APM without extending the APM Reporting Credit to all APM participants would be to retain the APM Quality Reporting Credit for all two-sided risk APM tracks but to remove this credit for participants in all one-sided risk tracks except for those APM Entities in the first 2 years—or first agreement period—of a MIPS APM.

We believe this approach would help ease the transition from MIPS to APM participation and ultimately into Advanced APM participation. However, this proposal would continue to provide the APM Quality Reporting Credit for participants in two-sided risk APMs who have not reached the QP threshold. In this way, we could create an incentive for APM participants to move towards Advanced APMs, even in situations where it is unlikely the participant would be able to reach the QP threshold.

(iv) Retain Different APM Quality Reporting Credits for Advanced APMs and MIPS APMs

Another available option would be to apply an APM Reporting Credit, as described above to all MIPS APM participants but base the available credit on the level of risk taken on by the MIPS APM. For example, the maximum 50 percent credit may continue to be available to APM Entities in Advanced APM tracks while the value of the credit may be limited to 25 percent for participants in one-sided risk tracks. We are soliciting comments on how we might best divide these tracks and address the advent of two-sided risk MIPS APMs that do not meet the nominal amount and financial risk standards in order to be considered an Advanced APM, and what an appropriate reporting credit would be for these tracks.

(v) Other Options

We seek comments and suggestions on other ways in which we could modify the APM scoring standard to continue to encourage MIPS eligible clinicians to join APMs, with an emphasis on encouraging movement toward participation in two-sided risk APMs that may qualify as Advanced APMs.

(e) MIPS APM Performance Feedback

As we discussed in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77270, and 82 FR 53704 through 53705, respectively), MIPS

eligible clinicians who are scored under the APM scoring standard will receive performance feedback under section 1848(q)(12) of the Act.

Regarding access to performance feedback, whereas split-TIN APM Entities and their participants can only access their performance feedback at the APM Entity group or individual MIPS eligible clinician level, MIPS eligible clinicians participating in the Shared Savings Program, which is a full-TIN APM, were able to access their performance feedback at the ACO participant TIN level for the 2017 performance period. However, due to confusion caused by the policy in cases, where not all eligible clinicians in a Shared Savings Program participant TIN received the APM Entity score, for example eligible clinicians that terminate before the first snapshot, we intend to better align treatment of Shared Savings Program ACOs and their participant TINs with other APM Entities and, where appropriate, with other MIPS groups. We will continue to allow ACO participant TIN level access to the APM Entity group level final score and performance feedback, as well as provide the APM Entity group level final score and performance feedback to individual MIPS eligible clinicians who bill through the TINs identified on the ACO's ACO participant list. However, we will also provide TIN level performance feedback to ACO participant TINs that will include the information that is available to all TINs participating in MIPS, including the applicable final scores for MIPS eligible clinicians billing under the TIN, regardless of their MIPS APM participation status.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2022 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts. As we transform MIPS through the MIPS Value Pathways (MVP) Framework as discussed in section III.K.3.a. of this proposed rule, we may propose modifications to our scoring methodology in future rulemaking as we continue to develop a methodology that emphasizes simplicity and that is understandable for MIPS eligible clinicians.

In this proposed rule, we are proposing policies to help eligible clinicians as they participate in the 2020 performance period/2022 MIPS payment year, and as we move beyond the transition years of the program.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus.

As we move towards the transformation of the program through the MVP Framework discussed in section III.K.3.a.(2) of this proposed rule, we anticipate we will revisit and remove many of our scoring policies such as the 3-point floor, bonus points, and assigning points for measures that cannot be scored against a benchmark through future rulemaking. As we propose to transform the MIPS program through MVPs, our goal is to incorporate ways to address these issues without developing special scoring policies. We refer readers to section III.K.3.a.(3)(d) of this proposed rule, for further discussion on scoring of MVPs.

In section III.K.3.d.(1) of this proposed rule, we discuss the limited proposals for our scoring policies as we anticipate future changes as we work to transform MIPS through MVPs. Specifically, we are proposing to: (1) Maintain the 3-point floor for measures that can be scored for performance; (2) develop benchmarks based on flat percentages in specific cases where we determine the measure's otherwise applicable benchmark could potentially incentivize inappropriate treatment; (3) continue the scoring policies for measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria; (4) maintain the cap on measure bonus points for high-priority measures and end-to-end reporting; and (5) continue the improvement scoring policy. In addition, we are requesting comment on future approaches to scoring the CAHPS for MIPS survey measure if new questions are added to the survey. These proposals are discussed in more detail in this section of the proposed rule.

(i) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1) for more on our policies for scoring performance on quality measures.

(A) Scoring Measures Based on Achievement

We established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years.

For the 2022 MIPS payment year, we are proposing to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period. As we move towards the proposed MVPs discussed in section III.K.3.a. of this proposed rule, we anticipate we will revisit and possibly remove the 3-point floor in future years. As a result, we will wait until there is further policy development under the proposed framework before proposing to remove the 3-point floor. Accordingly, we are proposing to amend § 414.1380(b)(1)(i) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. The number of measure achievement points received for each measure is determined based on the applicable benchmark decile category and the percentile distribution.

MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. A summary of the proposed policies for the CY 2020 MIPS performance period is provided in Table 43.

TABLE 43—QUALITY PERFORMANCE CATEGORY: PROPOSED SCORING POLICIES FOR THE CY 2020 MIPS PERFORMANCE PERIOD *

Measure type	Description	Scoring rules
Class 1	For the 2020 MIPS performance period: Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 70 percent for 2020.) ** ** We refer readers to section III.K.3.c.(1)(c) for our proposal to increase data completeness.	For the 2020 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.
Class 2	For the 2020 MIPS performance period: Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark (2) At least 20 cases.	For the 2020 MIPS performance period: 3 points.
Class 3	For the 2020 MIPS performance period: Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum	Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points.

* The Class 2 and 3 measure scoring policies are not applicable to CMS Web Interface measures or administrative claims-based measures.

For the 2022 MIPS payment year, we are proposing to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement. Accordingly, we are proposing to amend § 414.1380(b)(1)(i)(A)(*1*) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that except as provided in paragraph (b)(1)(i)(A)(2) (which relates to CMS Web Interface measures and administrative claims-based measures), for the 2019 through 2022 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(C) Modifying Benchmarks To Avoid the Potential for Inappropriate Treatment

We established at § 414.1380(b)(1)(ii) that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period. We also established at § 414.1380(b)(1)(i) that the number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution.

We believe all the measures in the MIPS program are of high standard as they have undergone extensive review prior to their inclusion in the program. MIPS measures go through the rulemaking process, and QCDR measures have an approval process before they are included in MIPS. We also believe our benchmarking generally provides an objective way to compare performance differences across different types of quality measures. However, we have heard concerns from stakeholders that for a few measures, the benchmark methodology may incentivize the inappropriate treatment of certain patients, in order for a clinician to achieve a score in the highest decile. Our scoring system already provides some protection from inappropriate treatment because all clinicians in the top 10 percent of the distribution receive the same 10-point score, thus a clinician with performance in the 90th percentile has no incentive to go higher. However, for certain measures with benchmarks set at very high or maximum performance in the top decile, we are concerned that these levels may not be representative and may not provide the most appropriate incentives for clinicians. Specifically, there are some measures that may have the potential to encourage clinicians to alter the clinical interaction with patients inappropriately, regardless of the individual patient's circumstances, in order to achieve that top decile performance level, for example, intermediate outcome measures that may encourage clinicians to over treat patients in order to achieve the highest performance level. Patient safety is our primary concern; therefore, we are proposing to establish benchmarks based on flat percentages in specific cases where we determine the measure's

otherwise applicable benchmark could potentially incentivize treatment that could be inappropriate for a particular patient type. Rather than develop benchmarks based on the distribution of scores we would base them on flat percentages such that any performance rate at or above 90 percent would be in the top decile and any performance rate above 80 percent would be in the second highest decile, and this would continue for the remaining deciles. We believe the measures that would fall under this methodology are high-priority or outcome measures for clinicians to focus on. However, we want to ensure that benchmarks are set to incentivize the most appropriate behavior, and ensure that our method for scoring against a benchmark accurately reflects performance and does not result in clinicians receiving low scores, despite adherence to the most appropriate treatment.

For the measures identified, we are proposing to use a flat percentage, similar to how the Shared Savings Program uses flat percentages to set benchmarks for measures with high performance. We selected this methodology for the following reasons: First, it is a straight-forward and simple methodology that currently exists for some MIPS measures that are collected through the CMS Web Interface. Second, because we are applying this methodology to measures with very high performance, we believe this approach is consistent with the Shared Saving Program approach established at § 425.502(b)(2)(ii) of using flat percentages to set benchmarks when many reporters demonstrate high achievement on a measure. The Shared Savings Program uses this method to avoid penalizing high ACO performance; however, in this case, we would be applying the flat percentages to ensure that the benchmark does not result in inappropriate and potentially harmful patient treatment. We believe this adjustment would provide additional protection to patients and reduce the potential incentive for inappropriate treatment of patients.

We propose that to determine whether a measure benchmark may not provide the most appropriate incentives for treatment, thus creating the potential for inappropriate treatment based on the patient's circumstances, CMS medical officers would assess if there are patients for whom it would be inappropriate to achieve the outcome targeted by the measure benchmark. This assessment will include reviews of factors such as whether the measure specifications allow for clinical judgment to adjust for inappropriate outcomes, if the benchmarks for any of the impacted measure's collection types could put these patients at risk by setting a potentially harmful standard for top decile performance, or whether the measure is topped out. The intent of the assessment is to have CMS medical officers determine whether certain measure benchmarks may have unintended consequences that put patients at risk and the measure benchmark should therefore move to a flat percentage. The assessment will take into account all available information, including from the medical literature, published practice guidelines, and feedback from clinicians, groups, specialty societies, and the measure steward. Before applying the flat percentage benchmarking methodology to any recommended measure, we would propose the modified benchmark for the applicable MIPS payment year through rulemaking. This policy would be effective beginning with the CY 2020 MIPS performance period (and thus the 2022 MIPS payment adjustment year). We also seek comment on future actions we should take to help us in determining which measures to apply the flat percentage benchmarking to; for example, convening a technical expert panel.

We have identified two measures for which we believe we need to apply benchmarks based on flat percentages to avoid potential inappropriate treatment—MIPS #1 (NQF 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (9%) and MIPS #236 (NQF 0018): Controlling High Blood Pressure. Although there are protections built into both of these measures, such as the use of less stringent requirements than current clinical guidelines, they lack comprehensive denominator exclusions and risk-adjustment or risk-stratification, which can lead to the possible over treatment of patients in order to meet numerator compliance. Overtreatment could lead to instances where the patient's blood sugar or blood pressure is lowered to a level that meets the measure standard but is too low for their optimum health given other coexisting medical conditions.

Because the factors for determining if a measure benchmark has the potential to cause inappropriate treatment may include both measure and benchmark considerations, we are concerned that all the benchmarks associated with the different collection types of a measure could be affected. Therefore, we are proposing to use the flat percentage benchmarks as an alternative to our standard method of calculating benchmarks by a percentile distribution of measure performance rates under for all collection types where the top decile for any measure benchmark is higher than 90 percent under the performance-based benchmarking methodology at § 414.1380(b)(1)(ii). We are limiting the application of the flat percentage methodology to all collection types where the top decile for any measure benchmark is higher than 90 percent so that our flat percentage methodology will actually reduce or remove the incentive for inappropriate care. If the top decile was originally below 90 percent, using the flat percentages would actually raise the level up to 90 percent and therefore provide a stronger incentive to provide inappropriate care in order to get the top score. We also seek comment on whether we should use a criteria different than applying it to collection types where the top decile would be higher than 90 percent if the benchmark was based on a distribution. For the two measures we are proposing to modify, we would not know which benchmarks and their associated collection types are impacted until we run our analysis; however, based on the benchmarks for the 2019 MIPS performance period, we would anticipate using the modified benchmarks for the Medicare Part B claims and the MIPS CQM collection types.

We considered whether we should rerun the benchmarks excluding those in the top decile but are concerned that the approach would add complexity to the program overall. We seek comment on whether we should consider different methodologies for the modified benchmarks such as excluding the top decile or increasing the required data completeness for the measure to a very high level (for example, 95 to 100 percent) and use performance period benchmarks rather than historical benchmarks.

We are proposing to add paragraph § 414.1380(b)(1)(ii)(C) to state that beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines has the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at § 414.1380(b)(1)(ii). We also propose to revise the text at § 414.1380(b)(1)(ii) to provide exceptions and to clarify the requirement that benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(ii) Request for Feedback on Additional Policies for Scoring the CAHPS for MIPS Survey Measure

We refer readers to § 414.1380(b)(1)(vii)(B) for more on our policy on reducing the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements.

In this proposed rule, we are not proposing any changes to the scoring of the CAHPS for MIPS survey Measure. However, to the extent consistent with our authority to collect such information under section 1848(q) of the Act, we are considering expanding the information collected in the CAHPS for MIPS survey measure, described in section III.K.3.c.(1) of this proposed rule, and seek comment on scoring. One consideration is adding narrative questions to the CAHPS for MIPS survey measure, which would invite patients to respond to a series of questions in free text, such as responding to open ended questions and describing their experience with care in their own words. We believe narratives from patients about their health care experiences would be helpful to other patients when selecting a clinician and can provide a valuable complement to standardized survey scores, both to help clinicians understand what they can do to improve care and to engage and inform patients about differences among their experiences of care. On the other hand, there may be concerns about the accuracy and usefulness of narrative information reported by patients. For more information on the rationale for adding narrative questions, we refer readers to section III.K.3.c.(1)(c)(i) of this proposed rule. In addition, we are interested in learning from organizations with experience scoring narrative information, including methodologies. We would work with stakeholders on user testing before proposing any such methodology in future rulemaking. We are also considering adding an additional CAHPS for MIPS survey question allowing patients to provide a score for their overall experience and satisfaction rating with a recent health care encounter, to capture the patient ''voice'' and provide patients with information useful to making a decision on clinicians, as detailed in section III.I.3.a.(1) of this proposed rule. We are interested in feedback regarding how to score this measure. The new questions could potentially be added to the calculation for a score for the CAHPS for MIPS survey measure. We would consider any changes for future notice and comment rulemaking.

(iii) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2019 PFS final rule (83 FR 35950), we finalized our proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen.

In this proposed rule, we do not propose any changes to this policy. However, we refer readers to section III.K.3.d.(2)(b)(ii)(A) of this proposed rule for discussion on the rare circumstances when we are unable to calculate a quality performance category score for a MIPS eligible clinician because they do not have applicable or available quality measures. If we are unable to score the quality performance category for a MIPS eligible clinician, then we will reweigh the clinician's quality performance category score according to the reweighting policies described in sections III.K.3.d.(2)(b)(iii) of this proposed rule.

(iv) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for more on the cap on high-priority measure bonus points for the first 3 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category.

In the CY 2019 PFS final rule (83 FR 59851), we finalized technical updates to § 414.1380(b)(1) to more clearly and concisely capture previously established policies in the section. During this effort we inadvertently added that a high priority measure must have a benchmark. This was not intended to be a policy change. We are clarifying that in order for a measure to qualify for high priority bonus points it must meet case minimum and data completeness and not have a zero percent performance. The measure does not need to have a benchmark. Accordingly, we propose to revise § 414.1380(b)(1)(v)(A)(*1*)(*i*) to provide that each high priority measure must meet the case minimum requirement at (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

We also removed high priority bonus points for CMS Web interface reporters in the CY 2019 PFS final rule (83 FR 59850 through 59851). We refer readers to the CY 2019 PFS final rule for further discussion on this policy.

In this proposed rule, we propose to maintain the cap on measure points for reporting high priority measures for the 2022 MIPS payment year. Accordingly, we propose to revise § 414.1380(b)(1)(v)(A)(*1*)(*ii*) to remove the years 2019, 2020, and 2021 and adding in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(v) Incentives To Use CEHRT To Support Quality Performance Category Submissions

We refer readers to § 414.1380(b)(1)(v)(B) for more on our policy assigning one bonus point for each quality measure submitted with end-to-end electronic reporting, under certain criteria.

In this proposed rule, we propose to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2022 MIPS payment year. We believe with the proposed framework for transforming MIPS through the MVPs discussed in section III.K.3.a. of this proposed rule, we can find ways in future years to incorporate eCQM measures without needing to incentivize end-to-end reporting with bonus points. As a result, we will wait until there is further policy development under the proposed framework before proposing to remove our policy of assigning bonus points for end-to-end electronic reporting. Accordingly, we propose to revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) to remove the years 2019, 2020, and 2021 and add in its place the years 2019 through 2022 to provide that for the 2019 through 2022 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(vi) Improvement Scoring for the MIPS Quality Performance Category Percent Score

We refer readers to § 414.1380(b)(1)(vi)(C)(*4*) for more on our policy stating that for the 2020 and 2021 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

In this proposed rule, we propose to continue our previously established

policy for the 2022 MIPS payment year and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 and 2021 MIPS payment year'' and adding in its place the phrase ''2019 through 2022 MIPS payment years'' to provide that for the 2020 through 2022 MIPS payment years, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Specifically, for the 2022 MIPS payment year, we will compare the MIPS eligible clinician's quality performance category achievement percent score for the 2020 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent for the 2019 MIPS performance period.

(c) Facility-Based Measurement Scoring Option for the Quality and Cost Performance Categories for the 2022 MIPS Payment Year

(i) Background

For our previously established policies regarding the facility-based measurement scoring option, we refer readers to both the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767) and the CY 2019 PFS final rule (83 FR 59856 through 59867). In the CY 2019 PFS proposed rule (83 FR 35962 through 35963), we requested comments on a number of issues and topics related to whether we should expand the facility-based scoring option to other facilities and programs in future years, particularly the use of end-stage renal disease (ESRD) and post-acute care (PAC) settings as the basis for facility-based measurement and scoring. We appreciate the many comments we received in response to this request. We are not proposing an expansion to other facility types as part of this rule but may consider addressing this issue in future rulemaking.

(ii) Facility-Based Measurement Eligibility

In the CY 2019 PFS final rule (83 FR 59856 through 59860), we established the policies that determine eligibility for scoring for facility-based measurement as an individual and as a group. In the CY 2019 PFS final rule, we established at § 414.1380(e)(2)(i)(C) that a MIPS eligible clinician is facility-based if the clinician can be attributed, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. While we do not propose any changes to the eligibility of facility-based measurement for individuals or groups, we are proposing to amend § 414.1380(e)(2)(i)(C) to improve clarity. Specifically, we propose to amend § 414.1380(e)(2)(i)(C) to state that a MIPS eligible clinician is facility-based if the clinician can be assigned, under the methodology specified in § 414.1380(e)(5), to a facility with a value-based purchasing score for the applicable period. We hope to avoid any ambiguity as we have used the term ''attribute'' and ''attribution'' in two ways. We have used the term to refer to the use of the facility's performance in place of the clinician's own performance (83 FR 59857). We have also used the term at § 414.1380(e)(2)(i)(C) to reference our method of connecting clinicians to a facility and indicate that the facility score will be the clinician's score. We believe these are related but distinct concepts; therefore, we are proposing to revise § 414.1380(e)(2)(i)(C) to use the term ''assign'' instead of ''attribute.'' We believe this change in language more clearly describes how a clinician receives a score under facility-based measurement while avoiding making any changes to our methods in determining eligibility for facility-based measurement or their score. This does not constitute a change in policy.

(iii) Facility-Based Measures for CY 2020 MIPS Performance Period/2022 MIPS Payment Year

For informational purposes, we are providing in Table 44 a list of the measures included in the FY 2021 Hospital VBP Program measure set that will be used in determining the quality and cost performance category scores for the CY 2020 MIPS performance period/ 2022 MIPS payment year. The FY 2021 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 20413). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. These measures are determined through separate rulemaking; the applicable rulemaking is usually the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) rule. We are using these measures, benchmarks, and performance periods for the purposes of facility-based measurement in accordance with § 414.1380(e)(1). The measures for FY 2021 Hospital VBP Program were summarized in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 41454 through 41455).

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TABLE 44: FY 2021 Hospital VBP Program Measures

Short Name	Domain/Measure Name	NQF #	Performance Period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)	January 1, 2019-December 31, 2019
Clinical Outcomes Domain			
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization	0230	July 1, 2016-June 30, 2019
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization	0229	July 1, 2016-June 30, 2019
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	September 1, 2017-June 30, 2019
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893	July 1, 2016-June 30, 2019
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550	April 1, 2016-March 31, 2019
Safety Domain			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	January 1, 2019-December 31, 2019
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139	January 1, 2019-December 31, 2019
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	January 1, 2019-December 31, 2019
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716	January 1, 2019-December 31, 2019
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717	January 1, 2019-December 31, 2019
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158	January 1, 2019-December 31, 2019

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(d) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to § 414.1380(b)(3), the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769), and the CY 2019 PFS final rule (83 FR 59867 through 59868). We also refer readers to § 414.1355 and the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662), and the CY 2019 PFS final rule (83 FR 59776 through 59785) for our previously established policies regarding the improvement activities performance category generally and section III.K.3.c.(3) of this proposed rule, where we discuss our proposals for the improvement activities performance category.

(e) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.K.3.c.(4) of this proposed rule, where we discuss our proposals for the Promoting Interoperability performance category.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c) and the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), CY 2018 Quality Payment Program final rule (82 FR 53769 through 53785), and CY 2019 PFS final rule (83 FR 59868 through 59878). In this proposed rule, we are proposing to continue the complex patient bonus for the 2022 MIPS payment year and to establish performance category reweighting policies for the 2022, 2023, and 2024 MIPS payment years.

(a) Complex Patient Bonus for the 2022 MIPS Payment Year

In the CY 2019 PFS final rule (83 FR 59869 through 59870), under the authority in section 1848(q)(1)(G) of the Act, we finalized at § 414.1380(c)(3) to maintain the complex patient bonus, which we previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776), of up to five points to be added to the final score for the 2021 MIPS payment year. The complex patient bonus was developed as a short-term solution to address the impact patient complexity

may have on MIPS scoring that we would revisit on an annual basis while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was twofold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. For a detailed description of the complex patient bonus finalized for prior MIPS payment years, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776) and CY 2019 PFS final rule (83 FR 59869 through 59870).

For the 2020 MIPS performance period/2022 MIPS payment year, we propose to continue the complex patient bonus as finalized for the 2019 MIPS performance period/2021 MIPS payment year and to revise § 414.1380(c)(3) to reflect this policy. Although we intend to maintain the complex patient bonus as a short-term solution, we do not believe we have sufficient information available at this time to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to include a different approach in this proposed rule. Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology for MIPS. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, enacted October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. ASPE completed its first report [134] in December 2016, which examined the effect of individuals' socioeconomic status on quality, resource use, and other measures under the Medicare program, and included analyses of the effects of Medicare's current value-based payment programs on providers serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. The second ASPE report is expected in October 2019 as required by the IMPACT Act, and will examine additional risk factors and data. We expect the second report will build on the analyses included in initial report and may provide additional insight for a long-term solution to addressing risk factors in MIPS. At this time, we do not believe additional data sources are available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

With newly available data from the Quality Payment Program, we considered whether the data still support the complex patient bonus at the final score level. We have replicated analyses similar to the ones presented in Table 27 of the CY 2018 Quality Payment Program final rule (82 FR 53776). However, our latest analyses use the data submitted for the Quality Payment Program for the 2017 MIPS performance period and assess eligibility and final scores based on the proposals we are making for the 2020 MIPS performance period/2022 MIPS payment year using the methodology described in the Regulatory Impact Analysis in section VI. of this proposed rule.

[134] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs (2016). Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

In the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776), when considering approaches for a complex patient bonus, we reviewed evidence to identify how indicators of patient complexity have an impact on performance under MIPS, as well as availability of data to implement the bonus. Specifically, we identified two potential indicators for complexity: Medical complexity as measured through Hierarchical Condition Category (HCC) risk scores; and social risk as measured through the proportion of patients with dual eligible status.

We identified these indicators because they are common indicators of patient complexity in the Medicare program and the data is readily available. Both of these indicators have been used in CMS programs to account for risk and both data elements are already publicly available for individual NPIs in the Medicare Physician and Other Supplier Public Use File (referred to as the Physician and Other Supplier PUF).

We divided clinicians and groups into quartiles based on average HCC risk score and percentage of dual eligible patients. To assess whether there was a difference in MIPS simulated scores by these two variables, we analyzed the effect of average HCC risk score and dual eligible ratio separately for groups and individuals. When looking at individuals, we focused on individuals that reported 6 or more measures (removing individuals who reported no measures or who reported less than 6 measures). We restricted our analysis to individuals who reported 6 or more measures because we wanted to look at differences in performance for those who reported the 6 measures which are generally required under MIPS if there are six measures that apply to the MIPS eligible clinician, rather than differences in scores due to MIPS eligible clinicians not fully reporting for MIPS.

We also ranked MIPS eligible clinicians by proportion of patients with dual eligibility as previously done in Table 27 of the CY 2018 Quality Payment Program final rule (82 FR 53776). We have updated the analysis by using the components of the complex patient bonus and dividing clinicians into quartiles. The preliminary results are shown in Table 45.

TABLE 45—MIPS SIMULATED AVERAGE FINAL SCORE * BY HCC RISK QUARTILE AND DUAL ELIGIBLE RATIO QUARTILE

HCC risk score	Estimated 2022 MIPS payment year final scores using data submitted for the quality payment program for the 2017 MIPS performance period	
	Individuals with 6+ measures *	Groups
Quartile 1—Lowest Average HCC	72.32	70.3
Quartile 2	72.58	77.59
Quartile 3	73.2	73.93
Quartile 4—Highest Average HCC	72.68	67.66
Dual Eligible Ratio		
Quartile 1—Low Proportion of Dual Status	73.51	73.04
Quartile 2	72.37	76.28
Quartile 3	72.16	72.21
Quartile 4—Highest Proportion of Dual Status	70.7	68.79

* We restricted our analysis to individuals who reported 6 or more measures because we wanted to look at differences in performance for those who reported the 6 measures which are generally required under MIPS if there are six measures that apply to the MIPS eligible clinician, rather than differences in scores due to MIPS eligible clinicians not fully reporting for MIPS.

Table 45 illustrates the average estimated MIPS final scores for individual MIPS eligible clinicians who submitted at least 6 measures (generally, those who fully report for MIPS quality) and for group reporters, stratified by the average HCC risk score and dual eligible ratio quartiles. For more detail on the original analysis, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53776).[135]

Overall, the analysis of preliminary data shows a consistent relationship between the dual eligible ratio quartiles and the average MIPS final scores only for individuals, where the average MIPS final score decreases as the quartile increases. We see slight differences in the average HCC risk score and dual eligible ratio quartiles for groups, but virtually no difference for average HCC risk score for individuals. However, we have only 1 year of data and more recent data may bring different results. In addition, we are awaiting a second report from ASPE in October 2019 that we expect will provide more direction for our approach to accounting for risk factors in MIPS. We are concerned that without the information from ASPE and without observing a clear trend that would require a change in our methodology, making any changes beyond our proposal to continue this policy would be premature at this time.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 through 77329 and 82 FR 53779 through 53785, respectively), as well as the CY 2019 PFS final rule (83 FR 59870 through 59878). Under our proposals in section III.K.3.c.(2)(a) of this proposed rule, the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year. Under our proposals in section III.K.3.c.(1)(b) of this proposed rule, the quality performance category would thus make up 40 percent of a MIPS eligible clinician's final score the 2022 MIPS payment year, 35 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year. Table 46 summarizes the weights proposed for each performance category.

TABLE 46—PROPOSED WEIGHTS BY MIPS PERFORMANCE CATEGORY FOR THE 2022 THROUGH 2024 MIPS PAYMENT YEARS

Performance category	2022 MIPS payment year (proposed)	2023 MIPS payment year (proposed) (percent)	2024 MIPS payment year (proposed) (percent)
Quality	40	35	30
Cost	20	25	30
Improvement Activities	15	15	15
Promoting Interoperability	25	25	25

[135] Data submitted for 2017 MIPS performance period was subject to different policies than later years of MIPS (due to the ''pick-your-pace'' approach in the first year of MIPS and the much lower performance threshold of 3 points).

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity for each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2019 PFS final rule (83 FR 59871 through 59876).

(A) Reweighting Performance Categories Due to Data That Are Inaccurate, Unusable, or Otherwise Compromised

Under current regulations at § 414.1380(c)(2), we assign different weights to the performance categories and redistribute weight from one category to another under specified circumstances where we have determined reweighting is appropriate. These circumstances do not currently include cases where a MIPS eligible clinician submits data that are inaccurate, unusable, or otherwise compromised (referred to in this section as ''compromised data''). If we determine a MIPS eligible clinician has submitted compromised data, we assign the clinician a score of zero for the performance category. Because compromised data is not currently a basis for reweighting, the determination that data are inaccurate, unusable or otherwise compromised is likely to reduce the clinician's final score and therefore may reduce the clinician's payment adjustments. However, we believe that reweighting of the applicable performance categories may be appropriate in rare cases. Specifically, we believe reweighting may be appropriate when a MIPS eligible clinician's data are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents.

In the CY 2018 Quality Payment Program final rule, we discussed our belief that extreme and uncontrollable circumstances, such as natural disasters, could cause the MIPS measures and activities to be unavailable to a MIPS eligible clinician (82 FR 53780 through 53783). For similar reasons, we believe that the measures and activities may not be available to a MIPS eligible clinician for the quality, cost, and improvement activities performance categories under section 1848(q)(5)(F) of the Act when data related to the measures and activities are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents. In addition, we believe data that are inaccurate, unusable or otherwise compromised due to circumstances that are outside of the control of the MIPS eligible clinician or its agents could constitute a significant hardship for purposes of the Promoting Interoperability performance category under section 1848(o)(2)(D) of the Act. Therefore, we are proposing a new policy to allow reweighing for any performance category if, based on information we learn prior to the beginning of a MIPS payment year, we determine data for that performance category are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the MIPS eligible clinician or its agents.

For purposes of this reweighting policy, we propose that reweighting take into account both what control the clinician had directly over the circumstances and what control the clinician had indirectly through its agents. The term agent as used in this proposal is intended to include any individual or entity, including a third party intermediary as described in § 414.1400, acting on behalf of or under the instruction of the MIPS eligible clinician We believe that reweighting is not appropriate if a clinician could exert influence over a third party intermediary or another party to prevent or remediate compromised data and does not do so. However, we believe reweighting is appropriate in certain circumstances that may be within the control of the clinician's third party intermediary if the clinician cannot alter that party's conduct. Such circumstances would exist if a clinician's third party intermediary could correct the clinician's compromised data and despite requests from the clinician the third party intermediary chose not to do so. In this example, the decision by the third party intermediary not to make the correction would demonstrate that the third party intermediary was not acting as an agent of the clinician and the third party intermediary's conduct would not preclude reweighting. We solicit comments on this approach and possible alternatives for balancing efforts to allow reweighting in circumstances in which clinicians are not culpable for compromised data while maintaining financial incentives for clinicians, third party intermediaries and other parties to prevent and correct compromised data.

We propose that our determination of whether reweighing will be applied under this policy can take into account any information known to the agency and we will consider the information we obtain on a case-by-case basis for reweighting. We anticipate considering information provided to us through routine communication channels for the Quality Payment Program by any submitter type as defined under § 414.1305, as well as other relevant information sources of which we are aware. We request that third party intermediaries, to the extent feasible, inform MIPS eligible clinicians if the third party intermediary believes their data may have been compromised. To the extent third party intermediaries believe that MIPS data may be compromised, we encourage them to provide us with a list of or other identifying information for all MIPS eligible clinicians who may have been affected by such issues, so that we may evaluate the circumstances in a timely manner. We also encourage MIPS eligible clinicians to contact us and self-identify if they believe they have compromised data; they should not rely solely on a third party intermediary to do so. We recognize that there may be scenarios when a MIPS eligible clinician or one or more of its agents becomes aware of potential data issues prior to submission of data. We solicit comment on whether and how our proposed reweighting policy should apply to these circumstances. We note that compromised data are not true, accurate or complete for purposes of § 414.1390(b) or § 414.1400(a)(5) and knowing submission of compromised

data may result in remedial action against the submitter. A MIPS eligible clinician should not submit data and should not allow the submission of his or her data if the MIPS eligible clinician knows that the data are inaccurate, unusable, or otherwise compromised.

We propose to determine whether the requirements for reweighting are met by assessing if: (1) The MIPS eligible clinician's data are inaccurate, unusable, or otherwise compromised; and (2) the data are compromised due to circumstances outside of the control of the MIPS eligible clinician or agent. We would make the determination of whether the clinician's data are inaccurate, unusable or otherwise compromised based on documentation of the issue and its demonstrated effect on data of the particular MIPS eligible clinician. As noted above, we propose to limit this policy to cases where data are compromised outside the control of the clinician or its agent because we do not want to create incentives for clinicians or third party intermediaries to knowingly submit compromised data and want to encourage clinicians and their agents to take reasonable efforts to correct data that they believe maybe not compromised. Factors relevant to whether the circumstances were outside the control of the clinician and its agents include: Whether the affected MIPS eligible clinician or its agents knew or had reason to know of the issue; whether the affected MIPS eligible clinician or its agents attempted to correct the issue; and whether the issue caused the data submitted to be inaccurate or unusable for MIPS purposes. We solicit feedback on these factors and whether there are additional factors we should consider to determine if there should be reweighing based on compromised data. If we determine that a MIPS eligible clinician's data were compromised and the conditions for reweighting are met, we propose to notify the clinician of this determination through the performance feedback that we provide under section 1848(q)(12) of the Act if feasible, or through routine communication channels for the Quality Payment Program. We emphasize that this proposed reweighting policy is solely intended to mitigate the potential adverse financial impact of compromised data on the MIPS eligible clinician; a determination under this proposed policy that data are compromised due to circumstances outside of the control of the MIPS eligible clinician and its agent and therefore that reweighting will occur for that clinician does not indicate and should not be interpreted to suggest that a third party intermediary or other individual or entity could not be held liable for the compromised data.

We are proposing to apply reweighting only in cases when we learn of the compromised data before the beginning of the associated MIPS payment year because we want to encourage MIPS eligible clinicians and their agents to inform us of these concerns in a timely basis so we can update our data sets timely, while minimizing the impacts to other stakeholders who utilize MIPS data. For example, the Physician compare website utilizes MIPS data to provide information to patients, consumers and other stakeholders when selecting a clinician or group. We are concerned that without the appropriate incentive to notify us in a timely manner, clinicians and their agents may delay disclosures that data may be compromised and with these delays the MIPS data could be in an increased state of flux which will reduce the usefulness of the data to stakeholders. We are interested in feedback on whether there are other factors we should consider when adopting a timeline for reweighting due to compromised data and whether the period should be broader. We seek comment on whether we should restrict our reweighting due to compromised data to instances when we learn the relevant information prior to the beginning of the MIPS payment year and whether there are other incentives for MIPS eligible clinicians to alert us to concerns about compromised data. We emphasize that if we determine a MIPS eligible clinician has submitted compromised data for a performance category during the associated payment year or at a later point, the MIPS eligible clinician would not qualify for reweighting under this proposal, instead for the performance categories with compromised data the clinician's performance category score would be zero and the scoring weight for the category would not be redistributed.

In sum, under the authority in sections 1848(q)(5)(F) and 1848(o)(2)(D) of the Act, we are proposing at § 414.1380(c)(2)(i)(A)*(9),* and (c)(2)(i)(C)*(10),* beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. In addition, we are proposing to amend § 414.1380(c)(2)(i)(C) to ensure that the reweighting proposed at § 414.1380(c)(2)(i)(C)*(10),* would not be voided by the submission of data for the Promoting Interoperability performance category as is the case with other significant hardship exceptions. We solicit comment in this proposal and alternatives to potentially mitigate the impact on MIPS eligible clinicians who through no fault of their own have data in a performance category that are inaccurate, unusable or are otherwise compromised.

We note that we previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77326 through 77328 and 82 FR 53778 through 53779). Therefore, if a MIPS eligible clinician is scored on fewer than two performance categories as a result of reweighting due to compromised data, he or she would receive a final score equal to the performance threshold.

(iii) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77325 through 77329 and 82 FR 53783 through 53785, 53895 through 53900), in the CY 2019 PFS final rule (83 FR 59876 through 59878), and at § 414.1380(c)(2)(ii) we established policies for redistributing the weights of performance categories for the 2019, 2020, and 2021 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories. Under these policies, we generally redistribute the weight of a performance category or categories to the quality performance category because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs.

Because the cost performance category was zero percent of a MIPS eligible clinician's final score for the 2017 MIPS performance period, we stated in the CY 2019 PFS proposed rule (83 FR 35970) that it is not appropriate to redistribute weight to the cost performance category for the 2019 MIPS performance period because MIPS eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. In addition, we were concerned that there would be limited measures in the cost performance category under our proposals for the 2019 MIPS performance period and stated that it

may be appropriate to delay shifting additional weight to the cost performance category until additional measures are developed. However, we also noted that cost is a critical component of the Quality Payment Program and believe placing additional emphasis on the cost performance category in future years may be appropriate. Therefore, we solicited comment on redistributing weight to the cost performance category in future years.

Several commenters expressed the belief that the weight of other performance categories should not be redistributed to the cost performance category. One commenter stated that the cost performance category weight should not be increased until additional cost measures are available and additional results of the episode-based cost measures are available. Another commenter expressed the belief that the cost performance category does not yet accurately assess the impact of a clinician's care on the total cost of care for a patient.

We do not believe it would be appropriate to redistribute weight from the other performance categories to the cost performance category for the 2022 MIPS payment year, except in scenarios in which the only other scored performance category is the improvement activities performance category. As described in section III.K.3.c.(2)(b)(v) of this proposed rule, we are proposing substantial changes to the MSPB and total per capital cost measures, as well as proposing to add 10 new episode-based measures. We believe it is appropriate to provide MIPS eligible clinicians additional time to adjust to these changes prior to redistributing weight to the cost performance category. Under the proposals we are making in this proposed rule, we would begin to redistribute more weight to the cost performance category beginning with the 2023 MIPS payment year, because MIPS eligible clinicians will have had more experience being scored on cost measures at that point, and will have had time to adjust to the changes to existing measures and new episode-based measures that we are proposing.

Under our existing policies, we redistribute weight from the other performance categories to the improvement activities performance category in certain scenarios. However, we have generally redistributed performance category weights more to the quality performance category to incentivize reporting on quality measures, and because MIPS eligible clinicians have had more experience with quality measure reporting from other CMS programs. Beginning with the 2022 MIPS payment year, we propose to not redistribute performance category weights to the improvement activities performance category in any scenario. For the improvement activities performance category, we are only assessing whether a MIPS eligible clinician completed certain activities (83 FR 59876 through 59878). Because MIPS eligible clinicians will have had several years of experience reporting under MIPS, we believe it is important to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. Therefore, we believe it is no longer appropriate to increase the weight of the improvement activities performance category above 15 percent under our redistribution policies. We note that in situations where the weights of both the quality and Promoting Interoperability performance categories are redistributed, cost would be weighted at 85 percent and improvement activities would be weighted at 15 percent. We believe this would help to reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. For example, when a clinician may be able to report on quality measures, but chooses not to report because they are located in an area affected by extreme and uncontrollable circumstances as identified by CMS and qualify for reweighting under § 414.1380(c)(2)(i)(A)(8).

For the 2022 MIPS payment year, we propose at § 414.1380(c)(2)(ii)(D) similar redistribution policies to our policies finalized for the 2021 MIPS payment year (83 FR 59876 through 59878), with minor modifications, as shown in Table 47. First, we have adjusted our redistribution policies to account for a cost performance category weight of 20 percent for the 2022 MIPS payment year. We are also proposing, in scenarios when the cost performance category weight is redistributed while the Promoting Interoperability performance category weight is not, to redistribute a portion of the cost performance category weight to the Promoting Interoperability performance category as well as to the quality performance category. We believe this is appropriate given our current focus on working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act (the Cures Act) (Pub. L. 115–233, enacted December 13, 2016) to ensure seamless but secure exchange of health information for clinicians and patients. While we have previously redistributed all of the cost performance category weight to the quality performance category (83 FR 59876 through 59878), we propose to redistribute 15 percent to the quality performance category and 5 percent to the Promoting Interoperability performance category for the 2022 MIPS payment year (*see* Table 47). This proposed change would emphasize the importance of interoperability without overwhelming the contribution of the quality performance category to the final score. We also propose to weight the improvement activities performance category at 15 percent and to weight the Promoting Interoperability performance category at 85 percent for the 2022 MIPS payment year when the quality and cost performance categories are each weighted at zero percent, to align with our focus on interoperability and pursuant to our proposal of not redistributing weight to the improvement activities performance category.

TABLE 47—PERFORMANCE CATEGORY REDISTRIBUTION POLICIES PROPOSED FOR THE 2022 MIPS PAYMENT YEAR

Reweighting scenario	Quality (percent)	Cost (percent)	Improvement activities (percent)	Promoting interoperability (percent)
No Reweighting Needed:				
—Scores for all four performance categories	40	20	15	25
Reweight One Performance Category:				
—No Cost	55	0	15	30
—No Promoting Interoperability	65	20	15	0
—No Quality	0	20	15	65

TABLE 47—PERFORMANCE CATEGORY REDISTRIBUTION POLICIES PROPOSED FOR THE 2022 MIPS PAYMENT YEAR—Continued

Reweighting scenario	Quality (percent)	Cost (percent)	Improvement activities (percent)	Promoting interoperability (percent)
—No Improvement Activities	55	20	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	15	85
—No Cost and no Improvement Activities	70	0	0	30
—No Promoting Interoperability and no Quality	0	85	15	0
—No Promoting Interoperability and no Improvement Activities	80	20	0	0
—No Quality and no Improvement Activities	0	20	0	80

In section III.K.3.c.(2)(a) of this proposed rule, we have proposed weights for the cost performance category of 25 and 30 percent for the 2023 and 2024 MIPS payment years, respectively. Because MIPS eligible clinicians will have had more experience being scored on cost measures, we believe it would be appropriate to begin redistributing even more of the performance category weights to the cost performance category beginning with the 2023 MIPS payment year. While we have proposed to redistribute weight to the cost performance category for the 2022 MIPS payment year in scenarios in which only the cost and improvement activities performance categories are scored, we believe that we should redistribute weight to the cost performance category in other scenarios beginning with the 2023 MIPS payment year. In general, we would redistribute performance category weights so that the quality and cost performance categories are almost equal. For simplicity, we would redistribute the weight in 5-point increments. If the redistributed weight cannot be equally divided between quality and cost in 5-point increments, we would redistribute slightly more weight to quality than cost. We believe that redistributing weight equally to quality and cost is consistent with our goal of greater alignment between the quality and cost performance categories as described in section III.K.3.c.(2) of this proposed rule. We would also continue to redistribute weight to the Promoting Interoperability performance category, but we would ensure that if the quality and cost performance categories are scored, they would have a higher weight than the Promoting Interoperability performance category. For example, beginning with the 2024 MIPS payment year, if the improvement activities performance category is the only performance category to be reweighted to zero percent, quality and cost would be 40 and 35 percent, respectively, and we would not increase the weight of the Promoting Interoperability performance category (weighted at 25 percent) so that it would not exceed the weight of the quality or cost performance categories. Our proposed redistribution polices for the 2023 and 2024 MIPS payment years, which we propose to codify at §§ 414.1380(c)(2)(ii)(E) and (F), are presented in Tables 47 and 48.

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TABLE 48: Performance Category Redistribution Policies Proposed for the 2023 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	35%	25%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	50%	35%	15%	0%
-No Quality	0%	40%	15%	45%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	65%	0%	0%	35%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	55%	45%	0%	0%
-No Quality and no Improvement Activities	0%	45%	0%	55%

TABLE 49: Performance Category Redistribution Policies Proposed for the 2024 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	45%	40%	15%	0%
-No Quality	0%	45%	15%	40%
-No Improvement Activities	40%	35%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	60%	0%	0%	40%
-No Promoting Interoperability and no Quality	0%	85%	15%	0%
-No Promoting Interoperability and no Improvement Activities	50%	50%	0%	0%
-No Quality and no Improvement Activities	0%	60%	0%	40%

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e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used in MIPS payment adjustment calculations, we refer readers to the CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343).

We are proposing to: (1) Set the performance threshold for the 2022 and 2023 MIPS payment years and (2) set the additional performance threshold for exceptional performance for the 2022 and 2023 MIPS payment years.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act includes a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional

MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies. The performance thresholds for the first 3 years of MIPS are presented in Table 50.

TABLE 50—PERFORMANCE THRESHOLDS FOR THE 2019 MIPS PAYMENT YEAR, 2020 MIPS PAYMENT YEAR, AND 2021 MIPS PAYMENT YEAR

	2019 MIPS payment year (points)	2020 MIPS payment year (points)	2021 MIPS payment year (points)
Performance Threshold	3	15	30

To determine a performance threshold to propose for the fourth year of MIPS (2020 MIPS performance period/2022 MIPS payment year) and the fifth year of MIPS (2021 MIPS performance period/2023 MIPS payment year), we are again relying upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018.

As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2022 MIPS payment year. In accordance with section 1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year would be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

To estimate the performance threshold for the 2024 MIPS payment year, we considered the actual MIPS final scores for MIPS eligible clinicians for the 2019 MIPS payment year and the estimated MIPS final scores for the 2020 MIPS payment year and 2021 MIPS payment year. As referenced in the CY 2019 PFS final rule, we analyzed the actual final scores for the first year of MIPS (the 2019 MIPS payment year) and found the mean final score was 74.01 points and the median final score was 88.97 points (83 FR 59881). In the Regulatory Impact Analysis (RIA) of the CY 2019 PFS final rule, we used data submitted for the first year of MIPS (2017 MIPS performance period/2019 MIPS payment year) and applied the scoring and eligibility policies for the third year of MIPS (2019 MIPS performance period/2021 MIPS payment year) to estimate the potential final scores for the 2021 MIPS payment year. The estimated mean final score for the 2021 MIPS payment year was 69.53 points and the median final score was 78.72 points (83 FR 60048). We also estimated mean and median final scores for the 2020 MIPS payment year of 80.3 points and 90.91 points, respectively, based on information in the regulatory impact analysis in the CY 2018 Quality Payment Program final rule (82 FR 53926 through 53950). Specifically, we used 2015 and 2016 PQRS data, 2014 and 2015 CAHPS for PQRS data, 2014 and 2015 VM data, 2015 and 2016 Medicare and Medicaid EHR Incentive Program data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility, the initial QP determination file for the 2019 payment year, the 2017 MIPS measure benchmarks, and other available data to model the final scores for clinicians estimated to be MIPS eligible in the 2020 MIPS payment year (82 FR 53930). We considered using the actual final scores for the 2020 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2019, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses for purposes of this proposed rule (although we intend to include those results in the final rule if available). We believe the data points based on actual data from the 2017 MIPS performance period/2019 MIPS payment year would be appropriate to use in our analysis in projecting the estimated performance threshold for the 2024 MIPS payment year. However, after we analyze the actual final scores for the 2020 MIPS payment year, if we see the mean or median final scores significantly increasing or decreasing, we would consider modifying our estimation of the performance threshold for the 2024 MIPS payment year accordingly.

We refer readers to Table 51 for potential values for estimating the performance threshold for the 2024 MIPS payment year based on the mean or median final score from prior periods.

TABLE 51—POTENTIAL VALUES FOR ESTIMATED PERFORMANCE THRESHOLD FOR THE 2024 MIPS PAYMENT YEAR BASED ON THE MEAN OR MEDIAN FINAL SCORE FOR THE 2019 MIPS PAYMENT YEAR; 2020 MIPS PAYMENT YEAR; AND 2021 MIPS PAYMENT YEAR

	2019 MIPS payment year * (points)	2020 MIPS payment year ** (points)	2021 MIPS payment year *** (points)
Mean Final Score	74.01	80.30	69.53
Median Final Score	88.97	90.91	78.72

Source: CY 2019 PFS final rule RIA * *** (83 FR 60048); CY 2018 Quality Payment Program final rule RIA ** (82 FR 53926 through 53950).
* Mean and median final scores based on actual final scores for 2019 MIPS payment year.
** Mean and median final scores based on information available in the RIA because actual final scores for the 2020 MIPS payment year were not available in time for this proposed rule.
*** Mean and median final scores based on estimated final scores from 2021 MIPS payment year.

We are choosing the mean final score of 74.01 points for the 2019 MIPS payment year as our estimate of the performance threshold for the 2024 MIPS payment year because it represents a mean based on actual data; is more representative of clinician performance because all final scores are considered in the calculation; is more achievable for clinicians, particularly for those that are new to MIPS; and is a value that falls generally in the middle of potential values for the performance threshold referenced in Table 51. In the CY 2019 PFS proposed rule, we requested comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which was based on the estimated mean final score for the 2019 MIPS payment year, and whether we should use the median instead of the mean (83 FR 35972). A few commenters supported the use of the mean rather than the median for determining the performance threshold because they believed this approach and the statutory requirement of a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year would provide a clear path and certainty and would allow for clinicians to budget, plan, and develop a long-term strategy for successful participation in MIPS.

We note that estimating the performance threshold for the 2024 MIPS payment year based on the mean final score for the 2019 MIPS payment year is only an estimation that we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act. We are proposing to use data from the 2019 MIPS payment year because it is the only MIPS final score data available and usable in time for the publication of this proposed rule. We acknowledge that via the 2020 MIPS payment year performance feedback, we have provided to MIPS eligible clinicians their calculated final scores. However, the mean and median of final scores for the 2020 MIPS payment year are not yet published. We anticipate that the mean and median data points for the 2020 MIPS payment year will be available for consideration prior to publication of the final rule and seek comment on whether and how we should use this information to update our estimates. We understand that using final scores from the early years of MIPS has numerous limitations and may not be similar to the distribution of final scores for the 2024 MIPS payment year. Eligibility and scoring policies changed in the initial years of the program. For example, beginning with the 2020 MIPS payment year, we increased the low-volume threshold compared to the 2019 MIPS payment year. We also added incentives for improvement scoring for the quality performance category and bonuses for complex patients and small practices, which could increase scores. Starting with the 2021 MIPS payment year, we modified our eligibility to include new clinician types and an opt-in policy, revised the small practice bonus, significantly revised the Promoting Interoperability performance category scoring methodology, and added a topped-out cap for certain topped out quality measures. As illustrated in Table 51, we estimated that the mean and median final scores for the 2020 MIPS payment year will be higher than for the 2019 MIPS payment year; however, we anticipate the final scores for the 2021 MIPS payment year will be lower. Recognizing the limitations of data for the 2019 MIPS payment year and the 2020 MIPS payment year, we are requesting comments on whether we should update or modify our estimates. We will propose the actual performance threshold for the 2024 MIPS payment year in future rulemaking.

Based on these analyses, we are proposing a performance threshold of 45 points for the 2022 MIPS payment year and a performance threshold of 60 points for the 2023 MIPS payment year to be codified at § 414.1405(b)(7) and (8), respectively. A performance threshold of 45 points for the 2022 MIPS payment year and 60 points for the 2023 MIPS payment year would be an increase that is consistent with the increase in the performance threshold from the 2020 MIPS payment year (15 points) to the 2021 MIPS payment year (30 points), and we believe it would allow for a consistent increase over time that provides a gradual and incremental transition to the performance threshold we will establish for the 2024 MIPS payment year, which we have estimated to be 74.01 points.

For example, if in future rulemaking we were to set the performance threshold for the 2024 MIPS payment year at 75 points (which is close to the mean final score for the 2019 MIPS payment year), this would represent an increase in the performance threshold of approximately 45 points from the 2021 MIPS payment year (that is, the difference from the Year 3 performance threshold of 30 points to a Year 6 performance threshold of 75 points). We believe an increase of approximately 15 points each year, from Year 3 through Year 6 of the MIPS program, would provide for a gradual and incremental transition toward a performance threshold that must be set at the mean or median final score for a prior period in Year 6 of the MIPS program.

We also believe this increase of 15 points per year could incentivize higher performance by MIPS eligible clinicians and that a performance threshold of 45 points for the 2022 MIPS payment year, and a performance threshold of 60 points for the 2023 MIPS payment year, represent a meaningful increase compared to 30 points for the 2021 MIPS payment year, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold. In section III.K.3.e.(4) of this proposed rule, we provide examples of the ways clinicians can meet or exceed the proposed performance threshold for the 2022 MIPS payment year.

We recognize that some MIPS eligible clinicians may not exceed the proposed performance thresholds either due to poor performance or by failing to report on an applicable measure or activity that is required. We also recognize the unique challenges for small practices and rural clinicians that could prevent them from meeting or exceeding the proposed performance thresholds and refer readers to sections III.K.3.a.(3)(b)(i) and III.K.3.a.(3)(b)(i)(A) of this proposed rule for a discussion of the participation of small and rural practices in MVPs and a request for feedback on small and rural practices participation in MVPs, respectively.

We invite public comment on our proposals to set the performance threshold for the 2022 MIPS payment year at 45 points and to set the performance threshold for the 2023 MIPS payment year at 60 points. We also seek comment on whether we should adopt a different performance threshold in the final rule if we determine that the actual mean or median final scores for the 2020 MIPS payment year are higher or lower than our estimated performance threshold for the 2024 MIPS payment year of 74.01 points. For example, if the actual mean or median final score for the 2020 MIPS payment year is closer to 85 points, should we finalize a higher performance threshold than currently proposed? Or if the mean or median values are lower, should we finalize a lower performance threshold? We anticipate the data will change over time and that the distribution of final scores will differ from one year to the next. We also seek comment on whether the increase should be more gradual for the 2022 MIPS payment year, which would mean a lower performance threshold (for example, 35 instead of 45 points), or whether the increase should be steeper (for example, 50 points). We also seek comment on alternative numerical values for the performance threshold for the 2022 MIPS payment year. For the 2023 MIPS payment year, we alternatively considered whether the performance threshold should be set at a lower or higher number, for example, 55 points or 65 points, and also seek comment on alternative numerical values for the performance threshold for the 2023 MIPS payment year.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act. Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500 million of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in section III.K.3.e.(2) of this proposed rule, we are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act to propose a performance threshold of 45 points for the 2022 MIPS payment year and to propose a performance threshold of 60 points for the 2023 MIPS payment year. As we also discussed in section III.K.3.e.(2) of this proposed rule, for the initial 5 years of MIPS, the special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year. For the 2022 MIPS payment year and the 2023 MIPS payment year, we are relying on the discretion afforded by the special rule and proposing to again decouple the additional performance threshold from the performance threshold.

For illustrative purposes, we considered what the numerical values would be for the additional performance threshold under one of the methods described in section 1848(q)(6)(D)(ii) of the Act: The 25th percentile of the range of possible final scores above the performance threshold. With a proposed performance threshold of 45 points, the range of total possible points above the performance threshold is 45.01 to 100 points and the 25th percentile of that range is 58.75, which is just more than one-half of the possible 100 points in the MIPS final score. We do not believe it would be appropriate to lower the additional performance threshold to 58.75 points because it is below the mean and median final scores for each of the prior performance periods that are referenced in Table 51. Similarly, with a proposed performance threshold for the 2023 MIPS payment year of 60 points, the range of possible points above the performance threshold is 60.01 to 100 points and the 25th percentile of that range is 69.99 points. We do not believe it would be appropriate to lower the additional performance threshold to 69.99 points because it is below or close to the mean and median final scores for each of the prior performance periods that are referenced in Table 51.

We are relying on the special rule under section 1848(q)(6)(D)(iii) of the Act to propose at § 414.1405(d)(6) to set the additional performance threshold for the 2022 MIPS payment year at 80 points and to propose at § 414.1405(d)(7) to set the additional performance threshold for the 2023 MIPS payment year at 85 points. These values are higher than the 25th percentile of the range of the possible final scores above the proposed performance threshold for the 2022 and 2023 MIPS payment years.

We originally proposed 80 points for the additional performance threshold for the 2021 MIPS payment year in the CY 2019 PFS proposed rule (83 FR 35973) although we finalized 75 points in the CY 2019 PFS final rule (83 FR 59886). In the CY 2019 PFS final rule, we noted the impact that proposed policy changes for the 2021 MIPS payment year could have on final scores as clinicians are becoming familiar with these changes and noted our belief that 75 points was appropriate for Year 3 of MIPS (83 FR 59883 through 59886). We also signaled our intent to increase the additional performance threshold in future rulemaking. (83 FR 59886).

We believe that 80 points and 85 points are minimal and incremental increases over the additional performance threshold of 75 points for the 2021 MIPS payment year. We also believe it is appropriate to raise the bar on what is rewarded as exceptional performance for Year 4 and for Year 5 of the MIPS program and that increasing the additional performance threshold each year will encourage clinicians to increase their focus on value-based care and enhance the delivery of high quality care for Medicare beneficiaries.

An additional performance threshold of 80 points and 85 points would each require a MIPS eligible clinician to participate and perform well in multiple performance categories. Generally, under the proposed performance category weights for the 2022 MIPS payment year discussed as section III.K.3.d.(2)(b) of this proposed rule, a MIPS eligible clinician who is scored on all four performance categories could receive a maximum of 40 points towards the final score for the quality

performance category or a maximum score of 65 points for participating in the quality performance category and Promoting Interoperability performance category, which are both below the proposed 80-point and 85-point additional performance thresholds. In addition, 80 points and 85 points are at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target.

For example, if a MIPS eligible clinician gets a perfect score for the improvement activities (15 percent), cost (20 percent), and Promoting Interoperability (25 percent) performance categories, but does not submit quality measures data, then the MIPS eligible clinician would only receive 60 points (0 points for quality performance category + 20 points for the cost performance category + 15 points for improvement activities performance category + 25 points for Promoting Interoperability performance category), which is below the proposed additional performance thresholds. We believe setting the additional performance threshold at 80 points and 85 points could increase the incentive for exceptional performance while keeping the focus on quality performance.

We note that under section 1848(q)(6)(F)(iv) of the Act, funding is available for additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act only through the 2024 MIPS payment year, which is the sixth year of the MIPS program. We believe it is appropriate to further incentivize clinicians whose performance meets or exceeds the additional performance threshold for the fourth and fifth years of the MIPS program. We recognize that setting a higher additional performance threshold may result in fewer clinicians receiving additional MIPS payment adjustments. We also note that a higher additional performance threshold could increase the maximum additional MIPS payment adjustment that a MIPS eligible clinician potentially receives if the funds available (up to $500 million for each year) are distributed over fewer clinicians that have final scores at or above the higher additional performance threshold.

We invite public comment on our proposals to set the additional performance threshold at 80 points for the 2022 MIPS payment year and at 85 points for the 2023 MIPS payment year. Alternatively, for the 2022 MIPS payment year, we considered whether the additional performance threshold should remain at 75 points or be set at a higher number, for example, 85 points, and also seek comment on alternative numerical values for the additional performance threshold for the 2022 MIPS payment year. We refer readers to sections VI.E.10.c.(3) and VI.F.2. of the RIA for the estimated maximum payment adjustments when the additional performance threshold is set at 80 points and at 85 points, respectively, for the 2022 MIPS payment year.

Alternatively, for the 2023 MIPS payment year, we also considered whether the additional performance threshold should remain at 80 points as proposed for the 2022 MIPS payment year or whether a different numerical value should be adopted for the 2023 MIPS payment year, and also seek comment on alternative numerical values for the additional performance threshold for the 2023 MIPS payment year. Additionally, in the event that we adopt different numerical values for the performance threshold in the final rule than proposed in section III.K.3.e.(2) of this proposed rule, we seek comment on whether we should adopt different numerical values for the additional performance threshold and how we should set those values. We also seek comment on how the distribution of the additional MIPS payment adjustments across MIPS eligible clinicians may impact exceptional performance by clinicians participating in MIPS. For example, the distribution of the additional MIPS payment adjustments could result in a higher additional MIPS payment adjustment available to fewer clinicians or could result in a lower additional MIPS payment adjustment available to a larger number of clinicians. We also remind readers that we anticipate the data will change over time and that the distribution of final scores will differ from one year to the next.

(4) Example of Adjustment Factors

In the CY 2019 PFS proposed rule (83 FR 35978 through 35981) and the CY 2019 PFS final rule (83 FR 59891 through 59894), we provided a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2021 MIPS payment year. We are updating the figure and tables based on the policies we are proposing in this proposed rule.

Figure 1 provides an example of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on the policies proposed for the 2022 MIPS payment year in this proposed rule. In Figure 1, the performance threshold is 45 points. The applicable percentage is 9 percent for the 2022 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2022 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 11.25 points based on the performance threshold of 45 points for the 2022 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 9 percent for the 2022 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 9 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be higher than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 45 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because the performance threshold is 45 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 9 percent.

Figure 1 illustrates an example of the slope of the line for the linear adjustments for the 2022 MIPS payment year, but it could change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.203. In this example, MIPS eligible clinicians with a final score equal to 100 would have a MIPS payment adjustment factor of 1.823 percent (9 percent ×

0.2026). (Note that this is prior to adding the additional payment adjustment for exceptional performance, which is explained below.)

The proposed additional performance threshold for the 2022 MIPS payment year is 80 points. An additional MIPS payment adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional MIPS payment adjustment factors is equal to $500 million. In Figure 1, the example scaling factor for the additional MIPS payment adjustment factor is 0.395. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 3.95 percent (10 percent × 0.395). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0182 + 0.0395 = 0.0578, for a total positive MIPS payment adjustment of 5.78 percent.

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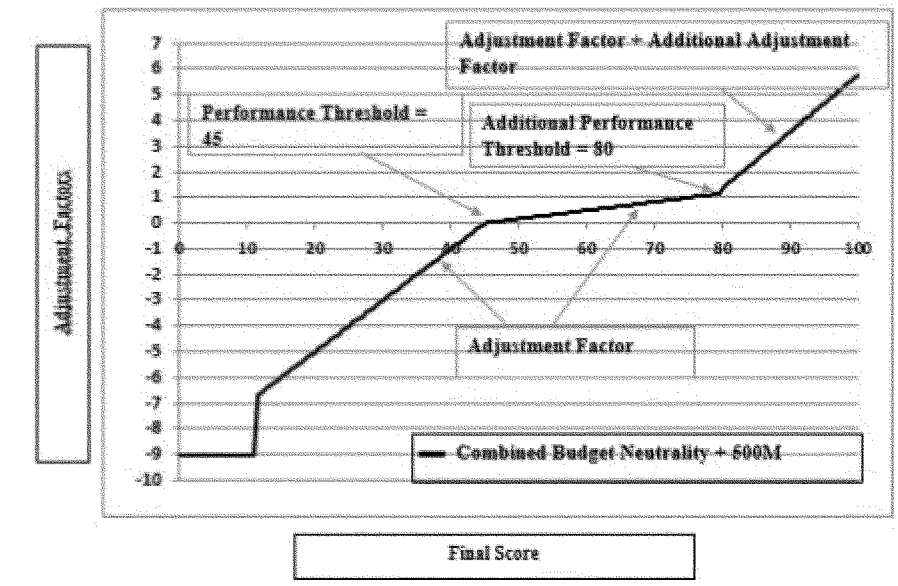
FIGURE 1: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Proposed Performance Threshold and Proposed Additional Performance Threshold for the 2022 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS clinicians with a final score of at least 80 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible clinicians would receive a positive MIPS payment adjustment factor.

Table 52 illustrates the changes in payment adjustments based on the final policies for the 2020 and 2021 MIPS payment years, and the proposed policies for the 2022 and 2023 MIPS payment years discussed in this proposed rule, as well as the statutorily required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 52: Illustration of Point System and Associated Adjustments Comparison between the 2020 MIPS Payment Year, the 2021 MIPS Payment Year, and the Proposed Policies for the 2022 MIPS Payment Year and the 2023 MIPS Payment Year

2020 MIPS payment year		2021 MIPS payment year		2022 MIPS payment year (proposed)		2023 MIPS payment Year (proposed)	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-3.75	Negative 5%	0.0-7.5	Negative 7%	0.0-11.25	Negative 9%	0.0-15.0	Negative 9%
3.76-14.99	Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale	7.51-29.99	Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale	11.26-44.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
15.0	0% adjustment	30.0	0% adjustment	45.0	0% adjustment	60.0	0% adjustment
15.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	30.01-74.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	45.01-79.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for final scores from 15.00 to 100.00. This sliding scale is multiplied by a	75.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for final scores from 30.00 to 100.00. This sliding scale is multiplied by a	80.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges

2020 MIPS payment year		2021 MIPS payment year		2022 MIPS payment year (proposed)		2023 MIPS payment Year (proposed)	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
	scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 80.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.		from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance

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We have provided updated examples below with the policies proposed for the 2022 MIPS payment year to demonstrate scenarios in which MIPS eligible clinicians can achieve a final score above the proposed performance threshold of 45 points based on our final policies.

Example 1: MIPS Eligible Clinician in Small Practice Submits 5 Quality Measures and 1 Improvement Activity

In the example illustrated in Table 53, a MIPS eligible clinician in a small practice reporting individually exceeds the performance threshold by performing at the median level for 5 quality measures via Part B claims collection type and one medium-weight improvement activity. The practice does not submit data for the Promoting Interoperability performance category, but does submit a significant hardship exception application which is approved; therefore, the weight for the Promoting Interoperability performance

category is redistributed to the quality performance category under the proposed reweighting policies discussed in section III.K.3.d.(2)(b)(iii) of this proposed rule. We also assumed the small practice has a cost performance category percent score of 50 percent. Finally, we assumed a complex patient bonus of 3 points which represents the average HCC risk score for the beneficiaries seen by the MIPS eligible clinician, as well as the proportion of Medicare beneficiaries that are dual eligible. There are special scoring rules for the improvement activities performance category which affect MIPS eligible clinicians in a small practice.

- Six measure achievement points for each of the 5 quality measures submitted at the median level of performance. We refer readers to § 414.1380(b)(1)(i) for further discussion of the quality performance category scoring policy. Because the measures are submitted via Part B claims, they do not qualify for the end-to-end electronic reporting bonus, nor do the measures submitted qualify for the high-priority bonus. The small practice bonus of 6 measure bonus points apply because at least 1 measure was submitted. Because the MIPS eligible clinician does not meet full participation requirements, the MIPS eligible clinician does not qualify for improvement scoring. We refer readers to § 414.1380(b)(1)(vi) for the full participation requirements for improvement scoring. Therefore, the quality performance category is (30 measure achievement points + 6 measure bonus points)/60 total available measure points + zero improvement percent score which is 60 percent.
- The Promoting Interoperability performance category weight is redistributed to the quality performance category so that the quality performance category score is worth 65 percent of the final score. We refer readers to section III.K.3.d.(2)(b)(iii) of this proposed rule for a discussion of this policy.
- MIPS eligible clinicians in small practices qualify for special scoring for improvement activities so a medium weighted activity is worth 20 points out of a total 40 possible points for the improvement activities performance category. We refer readers to § 414.1380(b)(3) for further detail on scoring policies for small practices for the improvement activities performance category.
- This MIPS eligible clinician exceeds the performance threshold of 45 points (but does not exceed the additional performance threshold). This score is summarized in Table 53.

TABLE 53—SCORING EXAMPLE 1, MIPS ELIGIBLE CLINICIAN IN A SMALL PRACTICE

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	60%	65%	39
Cost	50%	20%	10
Improvement Activities	20 out of 40 points—50%	15%	7.5
Promoting Interoperability	N/A	0% (redistributed to quality)	0
Subtotal (Before Bonuses)			56.5
Complex Patient Bonus			3
Final Score (not to exceed 100).			59.5

Example 2: Group Submission Not in a Small Practice

In the example illustrated in Table 54, a MIPS eligible clinician in a medium size practice participating in MIPS as a group receives performance category scores of 75 percent for the quality performance category, 50 percent for the cost performance category, and 100 percent for the Promoting Interoperability and improvement activities performance categories. There are many paths for a practice to receive a 75 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated at this amount. Again, for simplicity, we assume a complex patient bonus of 3 points. The final score is calculated to be 83 points, and both the performance threshold of 45 and the additional performance threshold of 80 are exceeded. In this example, the group practice exceeds the additional performance threshold and will receive the additional MIPS payment adjustment.

TABLE 54—SCORING EXAMPLE 2, MIPS ELIGIBLE CLINICIAN IN A MEDIUM PRACTICE

[A] Performance category	[B] Performance score	[C] Category weight (%)	[D] Earned points ([B] * [C] * 100)
Quality	75%	40	30
Cost	50%	20	10
Improvement Activities	40 out of 40 points—100%	15	15
Promoting Interoperability	100%	25	25
Subtotal (Before Bonuses)			80
Complex Patient Bonus			3
Final Score (not to exceed 100)			83

Example 3: Non-Patient Facing MIPS Eligible Clinician

In the example illustrated in Table 55, an individual MIPS eligible clinician that is non-patient facing and not in a small practice receives performance category scores of 50 percent for the quality performance category, 50 percent for the cost performance category, and 50 percent for 1 medium-weighted improvement activity. Again, there are many paths for a practice to receive a 50 percent score in the quality performance category, so for simplicity we are assuming the score has been calculated. Because the MIPS eligible clinician is non-patient facing, they qualify for special scoring for improvement activities and receive 20 points (out of 40 possible points) for the medium weighted activity. Also, this individual did not submit Promoting Interoperability measures and qualifies for the automatic redistribution of the Promoting Interoperability performance category weight to the quality performance category. Again, for simplicity, we assume a complex patient bonus of 3 points.

In this example, the final score is 53 and the performance threshold of 45 points is exceeded while the additional performance threshold of 80 points is not.

TABLE 55—SCORING EXAMPLE 3, NON-PATIENT FACING MIPS ELIGIBLE CLINICIAN

[A] Performance category	[B] Performance score	[C] Category weight	[D] Earned points ([B] * [C] * 100)
Quality	50%	65%	32.5
Cost	50%	20%	10
Improvement Activities	20 out of 40 points for 1 medium weight activity—50%.	15%	7.5
Promoting Interoperability	0%	0% (redistributed to quality)	0
Subtotal (Before Bonuses)			50
Complex Patient Bonus			3
Final Score (not to exceed 100).			53

We note that these examples are not intended to be exhaustive of the types of participants in MIPS nor the opportunities for reaching and exceeding the performance threshold.

f. Targeted Review and Data Validation and Auditing

For previous discussions of our policies for targeted review, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77353 through 77358).

We are proposing to: (1) Identify who is eligible to request a targeted review; (2) revise the timeline for submitting a targeted review request; (3) add criteria for denial of a targeted review request; (4) update requirements for requesting additional information; (5) state who will be notified of targeted review decisions and require retention of documentation submitted; and (6) codify the policy on scoring recalculations. These proposals are discussed in more detail in this proposed rule.

(1) Targeted Review

(a) Who Is Eligible To Request Targeted Review

In the CY 2017 Quality Payment Program final rule, we established at § 414.1385(a) that MIPS eligible clinicians and groups may submit a targeted review request and that these submissions could be with or without the assistance of a third party intermediary (81 FR 77353). In our efforts to minimize burden on MIPS eligible clinicians and groups, we believe it is important to allow designated support staff and third party intermediaries to submit targeted review requests on their behalf. To expressly acknowledge the role of designated support staff and third party intermediaries in the targeted review process, we are proposing to revise § 414.1385(a)(1) to state that a MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review. MIPS eligible clinicians and groups (including their designated support staff) can request a targeted review by logging into the QPP website at *qpp.cms.gov*, and after reviewing their performance feedback for the relevant performance period and MIPS payment year, they can submit a request for targeted review. An authorized third party intermediary as defined at § 414.1305, such as a qualified registry, health IT vendor, or QCDR, that does not have access to their clients' performance feedback still would be able to request a targeted review on behalf of their clients. Third party intermediaries do not have access to the performance feedback of MIPS eligible clinicians and groups; therefore, we will share an URL link to the Targeted Review Request Form with these designated entities. In the CY 2017 Quality Payment Program final rule, we established at § 414.1385(a)(2) that CMS will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted (81 FR 77353). We are proposing to redesignate this provision as § 414.1385(a)(4).

(b) Timeline for Targeted Review Requests

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(1) that MIPS eligible clinicians and groups have a 60-day period to submit a request for targeted review, which begins on the day we make available the MIPS payment adjustment factor, and if applicable the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors), for the MIPS payment year and ends on September 30 of the year prior to the MIPS payment year or a later date specified by CMS. During the first year of targeted review for MIPS, we allowed MIPS eligible clinicians and groups 90 days, with an additional 14-day extension, to submit a targeted review request. In response to user feedback, in December 2018, we made available revised performance feedback to MIPS eligible clinicians and groups who had filed a targeted review request. We believe it is important to ensure MIPS eligible clinicians and groups have an opportunity to review their revised

performance feedback prior to the application of the MIPS payment adjustment factors. We anticipate that by limiting the targeted review period to 60 days, we would be able to make available the revised performance feedback during October of the year prior to the MIPS payment year, which would be approximately 2 months earlier than what we were able to do for the first year of targeted review. Therefore, we are proposing to revise § 414.1385(a)(2) to state that all requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year, and to state that the targeted review request submission period may be extended as specified by CMS. We are proposing this change would apply beginning with the 2019 performance period.

(c) Denial of Targeted Review Requests

Each targeted review request is carefully reviewed based upon the information provided at the time the request is submitted. During the first year of targeted review, CMS received many targeted review requests that were duplicative. We continue to seek opportunities to limit burden and improve the efficiency of our processes. Therefore, we are proposing to revise § 414.1385(a)(3) to state that a request for a targeted review may be denied if: The request is duplicative of another request for targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. Notification will be provided to the individual or entity that submitted the targeted review request as follows:

- If the targeted review request is denied; in this case, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group.
- If the targeted review request is approved; in this case, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

(d) Request for Additional Information

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(3) that the MIPS eligible clinician or group may include additional information in support of their request for targeted review at the time the request is submitted, and if CMS requests additional information from the MIPS eligible clinician or group, it must be provided and received by CMS within 30 days of the request, and that non-responsiveness to the request for additional information may result in the closure of the targeted review request, although the MIPS eligible clinician or group may submit another request for targeted review before the deadline. Supporting documentation is a critical component of evaluating and processing a targeted review request. We may need to request supporting documentation, as each targeted review request is reviewed individually and by category. Therefore, we are proposing to add § 414.1385(a)(5) to state that a request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS's request. Non-responsiveness to CMS's request for additional information may result in a final decision based on the information available, although another request for a targeted review may be submitted before the end of the targeted review request submission period. Documentation can include, but is not limited to:

- Supporting extracts from the MIPS eligible clinician or group's EHR.
- Copies of performance data provided to a third party intermediary by the MIPS eligible clinician or group.
- Copies of performance data submitted to CMS.
- QPP Service Center ticket numbers.
- Signed contracts or agreements between a MIPS eligible clinician/group and a third party intermediary.

(e) Notification of Targeted Review Decisions

In the CY 2017 Quality Payment Program final rule (81 FR 77358), we finalized at § 414.1385(a)(4) that decisions based on the targeted review are final, and there is no further review or appeal. We are proposing to renumber this provision as § 414.1385(a)(7) and to add text to § 414.1385(a)(7) to state that CMS will notify the individual or entity that submitted the request for a targeted review of the final decision. To align with policies finalized at § 414.1400(g) regarding the auditing of entities submitting MIPS data, we are also proposing to add § 414.1385(a)(8) to state that documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

(f) Scoring Recalculations

In the CY 2017 Quality Payment Program final rule (81 FR 77353), we stated that if a request for targeted review is approved, the outcome of such review may vary. We stated, for example, we may determine that the clinician should have been excluded from MIPS, re-distribute the weights of certain performance categories within the final score (for example, if a performance category should have been weighted at zero), or recalculate a performance category score in accordance with the scoring methodology for the affected category, if technically feasible (81 FR 77353). Therefore, we are proposing to add § 414.1385(a)(6) to state that if a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to the measures, activities, performance categories, and final score, as well as the MIPS payment adjustment factors.

(2) Data Validation and Auditing

For previous discussions of our policies for data validation and auditing at § 414.1390, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77358 through 77362). Among other requirements, § 414.1390(b) establishes that all MIPS eligible clinicians and groups that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted is true, accurate and complete. MIPS data that are inaccurate, incomplete, unusable or otherwise compromised can result in improper payment. Despite these existing obligations, we have received inquiries regarding perceived opportunities to selectively submit data that are unrepresentative of the MIPS performance of the clinician or group. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as ''cherry-picking,'' results in data submissions that are not true, accurate or complete. A clinician or group cannot certify that data submitted to CMS are true, accurate and complete to the best of its knowledge if they know the data submitted is not representative of the clinician's or group's performance. Accordingly, a clinician or group that submits a certification under § 414.1390(b) in connection with the

submission of data they know is cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS believes cherry-picking of data may be occurring, we may subject the MIPS eligible clinician or group to auditing in accordance with § 414.1390(a) and in the case of improper payment a reopening and revision of the MIPS payment adjustment in accordance with § 414.1390(c).

g. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 17 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), and the CY 2019 PFS final rule (83 FR 59894 through 59910) for our previously established policies regarding third party intermediaries.

In this proposed rule, we propose to make several changes. We propose to establish new requirements for MIPS performance categories that must be supported by QCDRs, qualified registries, and Health IT vendors. We are proposing to modify the criteria for approval as a third party intermediary, and establish new requirements to promote continuity of service to clinicians and groups that use third party intermediaries for their MIPS submissions. With respect to QCDRs, we are also proposing requirements to: Engage in activities that will foster improvement in the quality of care; and enhance performance feedback requirements. These QCDR proposals would also affect the self-nomination process. We are also proposing to update considerations for QCDR measures. With respect to qualified registries, we are also proposing to require enhanced performance feedback requirements. Finally, we are clarifying the remedial action and termination provisions applicable to all third party intermediaries.

Because we believe that third party intermediaries, such as QCDRs, represent a useful path to fulfilling MIPS requirements while reducing the reporting burden for clinicians, we believe the proposals discussed in this section justify the collection of information and regulatory impact burden estimates discussed in sections IV. and VI. of this proposed rule, respectively, for additional information on the costs and benefits.

(1) Proposed Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088) for our current policy regarding the types of MIPS data third-party intermediaries may submit. In sum, the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. Through education and outreach, we have become aware of stakeholders' desires to have a more cohesive participation experience across all performance categories under MIPS. Specifically, we have heard of instances where clinicians would like to use their QCDR or qualified registry for reporting the improvement activities and promoting interoperability performance categories, but their particular third party intermediary does not support all categories, only quality. Based on this feedback and additional data regarding QCDRs and qualified registries respectively, which are discussed further below, we believe it is reasonable to strengthen our policies at § 414.1400(a)(2), and require QCDRs and qualified registries to support three performance categories: Quality; improvement activities; and Promoting Interoperability. Accordingly, we propose to amend § 414.1400(a)(2) to state that beginning with the 2021 performance period and for all future years, for the MIPS performance categories identified in the regulation, QCDRs and qualified registries must be able to submit data for each category, and Health IT vendors must be able to submit data for at least one category. We solicit feedback on the benefits and burdens of this proposal, including whether the requirement to support all three identified categories of MIPS performance data should extend to health IT vendors.

However, we recognize the need to create an exception to allow QCDRs and qualified registries that only represent MIPS eligible clinicians that are eligible for reweighting under the Promoting Interoperability performance category. For example, as discussed in the CY 2019 PFS final rule (83 FR 59819 through 59820), physical therapists generally are eligible for reweighting of the Promoting Interoperability performance category to zero percent of the final score; therefore, under this exception, a QCDR or qualified registry that represents only physical therapists that reweighted the Promoting Interoperability performance category to zero percent of the final score, would not be required to support the Promoting Interoperability performance category. Therefore, we are proposing to revise § 414.1400(a)(2)(iii) to state that for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4) or (5) or § 414.1380(c)(2)(i)(C)(1)–(7) or § 414.1380(c)(2)(i)(C)(9). We refer readers to section III.K.3.c.(4) of this proposed rule for additional information on the clinician types that are eligible for reweighting the Promoting Interoperability performance category. We anticipate using the self-nomination vetting process to assess whether the QCDR or qualified registry is subject to our proposed requirement to support reporting the Promoting Interoperability performance category. We solicit comments on this proposal, including the scope of the proposed exception from the Promoting Interoperability reporting requirement for certain types of QCDRs and qualified registries. Specifically, we solicit comment on whether we should more narrowly tailor, or conversely broaden, the proposed exceptions for when QCDRS and qualified registries must support the Promoting Interoperability performance category.

(2) Approval Criteria for Third Party Intermediaries

We refer readers to § 414.1400(a)(4) and the CY 2019 PFS final rule (83 FR 59894 through 59895; 60088) for previously finalized policies related to the approval criteria for third party intermediaries.

Based on experience with third party intermediaries thus far, in this proposed rule we are proposing to adopt two additional criteria for approval at § 414.1400(a)(4) to ensure continuity of services to MIPS eligible clinicians, groups, and virtual groups that utilize the services of third party intermediaries. Specifically, we have experienced instances where a third party intermediary withdraws mid-performance period, which impacts the clinician or group's ability to participate in the MIPS program, through no fault of their own. We are proposing two

changes to help prevent these disruptions. First, we are proposing at § 414.1400(a)(4) to add a new paragraph (v) to establish that a condition of approval for a third party intermediary is for the entity to agree to provide services for the entire performance period and applicable data submission period. In addition, we are proposing at § 414.1400(a)(4) to add a new paragraph (vi) to establish that a condition of approval is for third party intermediary to agree that prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary according to a CMS approved a transition plan. We believe it is important to condition the approval of a third party intermediary on the entity agreeing to follow this process so that in the case a third-party intermediary fails to meet its obligation under the proposed new § 414.1400(a)(4)(v) to provide services for the entire performance period and corresponding data submission period, the third party intermediary and the clinicians, groups, and virtual groups it serves have common expectations of the support the third party intermediary will provide to its users in connection with its withdrawal. We believe these proposed conditions of approval will help ensure that entities seeking to become approved as third party intermediaries are aware of the expectations to provide continuous service for the duration of the entire performance period and corresponding data submission period, will help reduce the extent to which the clinicians, groups, and virtual groups are inadvertently impacted by a third party intermediary withdrawing from the program, and will help clinicians, groups, and virtual groups avoid additional reporting burden that may result from withdrawals mid-performance period. We note that under this proposal, if CMS determines that a third party intermediary has ceased to meet either of these proposed new criteria for approval, CMS may take remedial action or terminate the third party intermediary in accordance with § 414.1400(f). We also refer readers to sections III.K.3.g.(3) and III.K.3.g.(4) where we discuss these proposals for QCDRs and qualified registries specifically.

(3) Qualified Clinical Data Registries (QCDRs)

In this proposed rule, we propose to update: (a) QCDR approval criteria; and (b) various policies related to QCDR measures. These proposals would also affect the QCDR self-nomination process.

(a) QCDR Approval Criteria

We generally refer readers to section 1848(m)(3)(E) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012, which requires the Secretary to establish requirements for an entity to be considered a Qualified Clinical Data Registry (QCDR) and a process to determine whether or not an entity meets such requirements. We refer readers to section 1848(m)(3)(E)(i), (v) of the Act, the CY 2019 PFS final rule (83 FR 60088), and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries and QCDR approval criteria. In this proposed rule, we are proposing to add to those policies to require QCDRs to: (a) Support all three performance categories where data submission is required; (b) engage in activities that will foster improvement in the quality of care; and (c) enhance performance feedback requirements.

(i) Requirement for QCDRs To Support All Three Performance Categories Where Data Submission Is Required

We also refer readers to section III.K.3.g.(1) above, where we propose to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In this section, we discuss QCDRs specifically. As previously stated in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), section 1848(q)(1)(E) of the Act encourages the use of QCDRs in carrying out MIPS. Although section 1848(q)(5)(B)(ii)(I) of the Act specifically requires the Secretary to encourage MIPS eligible clinicians to use QCDRs to report on applicable measures for the quality performance category, and section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs, the statute does not specifically address use of QCDRs for the other MIPS performance categories (81 FR 77363). Although we previously could have limited the use of QCDRs to assessing only the quality performance category under MIPS and providing performance feedback, we believed (and still believe) it would be less burdensome for MIPS eligible clinicians if we expand QCDRs' capabilities (81 FR 77363). By allowing QCDRs to report on quality measures, improvement activities, and Promoting Interoperability measures, we alleviate the need for individual MIPS eligible clinicians and groups to use a separate mechanism to report data for these performance categories (81 FR 77363). It is important to note that QCDRs do not need to submit data for the cost performance category since these measures are administrative claims-based measures (81 FR 77363).

As noted above, based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability.

Through education and outreach, we have become aware of stakeholders' desires to have a more cohesive participation experience across all performance categories under MIPS. Specifically, we have heard of instances where clinicians would like to use their QCDR for reporting the improvement activities and promoting interoperability performance categories, but their particular QCDR does not support all categories, only quality. This results in the clinician needing to enter into a business relationship with another third party to complete their MIPS reporting or leverage a different submitter type or submission type, which can create additional burden to the clinician. We believe that requiring QCDRs to be able to support these performance categories will be a step towards addressing stakeholders concerns on having a more cohesive participation experience across all performance categories under MIPS. In addition, we believe this proposal will help to reduce the reporting burden MIPS eligible clinicians and groups face when having to utilize multiple submission mechanisms to meet the reporting requirements of the various performance categories. Furthermore, as we move to a more cohesive participation experience under the MIPS Value Pathways (MVP), as discussed in section III.K.3.a., Transforming MIPS: MIPS Value Pathways Framework, we believe this proposal will assist clinicians in that transition.

Based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92

QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting all three performance categories. The 2019 QCDR qualified posting is available in the QPP Resource Library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/347/2019%20QCDR%20Qualified%20Posting_Final_v3.xlsx*. In addition, in our review of prior data through previous qualified postings for the 2017 and 2018 performance periods, we have observed that a majority of the QCDRs participating in the program supported the three performance categories that require data submission. In 2017, 73 percent (approximately 83 QCDRs) and in 2018, 73 percent (approximately 110 QCDRs) have supported all three performance categories. Based on this data, we believe it is reasonable to want to continue to strengthen our policies at § 414.1400(a)(2), to require that QCDRs have the capacity to support the reporting requirements of the quality, improvement activities, and promoting interoperability performance categories.

Therefore, beginning with the 2021 performance period and for future years, we propose to require QCDRs to support three performance categories: Quality, improvement activities, and Promoting Interoperability. Additionally, for reasons, as discussed above, we propose to amend § 414.1400(a)(2) to state beginning with the 2021 performance period and for all future years, for the following MIPS performance categories, QCDRs must be able to submit data for all categories, and Health IT vendors must be able to submit data for at least one category: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability with an exception. As discussed in section III.K.3.g.(1) of this proposed rule, we are proposing that based on the proposed amendment to § 414.1400(a)(2)(iii), for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4), (c)(2)(i)(A)(5), (c)(2)(i)(C)(1) through (c)(2)(i)(C)(7), or (c)(2)(i)(C)(9). As part of this proposal, we would require QCDRs to attest to the ability to submit data for these performance categories, as applicable, at time of self-nomination.

(ii) Requirement for QCDRs To Engage in Activities That Will Foster Improvement in the Quality of Care

We generally refer readers to section 1848(m)(3)(E)(i) and (v) of the Act, which requires the Secretary to establish requirements for an entity to be considered a qualified clinical data registry and a process to determine whether or not an entity meets such requirements. Section 1848(m)(3)(E)(ii)(IV) of the Act provides that in establishing such requirements, the Secretary must consider whether an entity, among other things, supports quality improvement initiatives for participants.

As detailed at § 414.1305(1) a QCDR means: For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

Although ''improvement in the quality of care'' is broadly included under paragraph (2) of the definition of a QCDR at § 414.1305 in the 2019 PFS final rule (83 FR 59897), we want to further clarify how a QCDR can be successful in fostering improvement in the quality of care provided to patients by clinicians and groups. We understand putting parameters around exactly what improvement in the quality of care may be can be difficult due to the varying nature of QCDRs organizational structures. For example, we have QCDRs that are founded by both large and small specialty societies, and healthcare systems where the volumes of services, available resources, and volume of members may vary. However, we believe QCDRs should enhance education and outreach to clinicians and groups to improve patient care.

The definition of qualified clinical data registry (QCDR) at § 414.1305(2) currently states that beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. In this proposed rule, we are proposing policies with regards to ''foster improvement in the quality of care.''

Therefore, we are proposing to add § 414.1400(b)(2)(iii) that beginning with the 2023 MIPS payment year, the QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives. Quality improvement services may be broad, and do not necessarily have to be specific towards an individual clinical process. An example of a broad quality improvement service would be for the QCDR to provide reports and educating clinicians on areas of improvement for patient populations by clinical condition for specific clinical care criteria. Furthermore, an example of an individual clinical process specific quality improvement service would be if the QCDR supports a metric that measures blood pressure management, the QCDR could use that data to identify best practices used by high performers and broadly educate other clinicians and groups on how they can improve the quality of care they provide. We believe educational services in quality improvement for eligible clinicians and groups would encourage meaningful and actionable feedback for clinicians to make improvements in patient care. To be clear, these QCDR quality improvement services would be separate and apart from any activities that are reported on under the improvement activities performance category. We believe improvement activities can be distinguished from quality improvement services, because they are actions taken by MIPS eligible clinicians under the improvement activities performance category. Improvement activities means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes (§ 414.1305). Quality improvement services, on the other hand, would be actions taken by the QCDR. While these QCDR quality improvement services could potentially overlap with an improvement activity, requirements for the improvement activities performance category would still apply to MIPS eligible clinicians and groups.

We are proposing to require QCDRs to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. We intend on including the QCDR's approved quality improvement services in the qualified posting for each approved QCDR.

(iii) Enhanced Performance Feedback Requirement

Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through QCDRs. In addition, in establishing the requirements, the Secretary must consider, among other things, whether an entity provides timely performance reports to participants at the individual participant level (section 1848(m)(3)(E)(ii)(III) of the Act). Currently, CMS requires QCDRs to provide timely performance feedback at least 4 times a year on all of the MIPS performance categories that the QCDR reports to CMS (82 FR 53812). Based on our experiences thus far under the Quality Payment Program, we agree that providing feedback at least 4 times a year is appropriate. However, in the future CMS would like to see, and therefore encourages QCDRs, to provide timely feedback on a more frequent basis more than 4 times a year. Receipt of more frequent feedback will help clinicians and groups make more timely changes to their practice to ensure the highest quality of care is being provided to patients. We see value in providing more timely feedback to meet the objectives [136] of the Quality Payment Program in improving the care received by Medicare beneficiaries, lowering the costs to the Medicare program through improvement of care and health, and advance the use of healthcare information between allied providers and patients. We also believe there is value in this performance feedback, and therefore, encourage QCDRs to work with their clinicians to get the data in earlier in the reporting period so the QCDR can give meaningful, timely feedback.

In the QCDR performance feedback currently being provided to clinicians and groups, we have heard from stakeholders that that not all QCDRs provide feedback the same way. We have heard through stakeholder comments that some QCDR feedback contains information needed to improve quality, whereas other QCDR feedback does not supply such information due to the data collection timeline. Additionally, we believe that clinicians would benefit from feedback on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure or QCDR measure) within the QCDR they are reporting through, so they can identify areas of measurement in which improvement is needed, and furthermore, they can see how they compare to their peers based within a QCDR, since the feedback provided by the QCDR would be limited to those who reported on a given measure using that specific QCDR.

Therefore, we are proposing a change so that QCDRs structure feedback in a similar manner. We propose a new paragraph at § 414.1400(b)(2)(iv), beginning with the 2023 MIPS payment year, to require that QCDRs provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period. We are also soliciting comment on other exceptions that may be necessary under this requirement.

We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. We believe QCDR internal comparisons can still help MIPS eligible clinicians identify areas where further improvement is needed. The ability for MIPS eligible clinicians to be able to know in real time how they are performing against their peers, within a QCDR, provides immediate actionable feedback. We believe this provides value gained for clinicians as the majority of QCDRs are specialty specific or regional based, therefore the clinician can gain peer comparisons that are specific to their peer cohort, which can be specialty specific or locality based.

Furthermore, we are also proposing to strengthen the QCDR self-nomination process at § 414.1400(b)(1) to add that beginning with the 2023 MIPS payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(b)(2)(iv)).

In addition, the current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st as described at § 414.1325(e)(1). As discussed above, we have heard from QCDR stakeholders that in some instances clinicians wait until the end of the performance period to submit data to the third party intermediary, who are then unable to provide meaningful feedback to their clinicians 4 times a year. Therefore, we are also seeking comment for future notice-and-comment rulemaking on whether we should require MIPS eligible clinicians, groups, and virtual groups who utilize a QCDR to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st). We are also seeking comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback and the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

(b) QCDR Measures

We refer readers to § 414.1400(b)(1), the CY 2018 Quality Payment Program final rule (82 FR 53814) and the CY 2019 PFS final rule (83 FR 59898 through 59900) for our previously established policies for the QCDR measure self-nomination process. In this proposed rule, we are proposing policies related to: (a) Considerations for QCDR measure approval; (b) requirements for QCDR measure approval; (c) considerations for QCDR measure rejections; (d) the approval process; and (e) QCDR measures that have failed to reach benchmarking thresholds. These are discussed in detail below.

(c) QCDR Measure Requirements

(i) QCDR Measure Considerations and Requirements for Approval or Rejection

Through education and outreach, we have heard stakeholders' concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, and believe our proposals will help to ensure that the measures made available in MIPS are meaningful to a clinician's scope of practice. In this proposed rule, we are proposing to codify established QCDR measure considerations and propose, beginning with the CY 2021 performance period, a number of QCDR measure specific requirements, that would generally align with MIPS measure policies, which can be found in the CY 2018 Quality Payment Program final rule (82 FR 53636), and as described in section III.K.3.c.(1) of this proposed rule.

[136] Quality Payment Program Overview. *https://qpp.cms.gov/about/qpp-overview.*

(A) QCDR Measure Considerations

(aa) Previously Finalized QCDR Measure Considerations

We generally refer readers to the § 414.1400(b)(3), CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) and the CY 2019 PFS final rule (83 FR 59900 through 59902) for previously finalized standards and criteria used for selecting and approving QCDR measures. QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis to determine whether they are appropriate for the program (82 FR 53811). The QCDR measure review process occurs after the self-nomination period closes on September 1st. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639).

In the CY 2019 PFS final rule (83 FR 59902), we finalized our proposal to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

In this proposed rule, we propose to codify a number of those previously finalized QCDR measure considerations (83 FR 59902). We are proposing to amend § 414.1400 by adding § 414.1400(b)(3)(iv) to include the following previously finalized QCDR measure considerations for approval:

- Preference for measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain of care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost, and resource use.

More information on QCDR measure approval criteria can be found in the QCDR/Qualified Registry Self-Nomination Tool-Kit in the QPP Resource Library. We refer readers to section III.K.3.g.(3)(c)(i)(B) of this rule where we are proposing to change the following previously finalized considerations into requirements:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

(bb) New QCDR Measure Considerations for Approval

(AA) QCDR Measure Availability

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we finalized a policy beginning with the 2018 performance period, that allowed QCDRs to seek permission from another QCDR to use an existing and approved QCDR measure. If a QCDR would like to report on an existing QCDR measure that is owned by another QCDR, they must have permission from the QCDR that owns the measure that they can use the measure for the performance period. Permission must be granted at the time of self-nomination, so that the QCDR that is using the QCDR measure can include written proof of permission for CMS review and approval. We also finalized in the CY 2018 Quality Payment Program final rule (82 FR 53814) that once QCDR measures are approved, we will assign QCDR measure IDs, and the same measure IDs must be used by the other QCDRs that have permission to also report on the measure.

We generally encourage QCDR measure owners to permit other QCDRs to report their measures on behalf of MIPS eligible clinicians for purposes of MIPS. To the extent that QCDR measure owners limit the availability of their measures, such limitations may adversely affect a QCDR's ability to benchmark the measure, the robustness of the benchmark, or the comparability of MIPS eligible clinicians' performance results on the measure. For these reasons, we propose to amend § 414.1400 to add paragraph (b)(3)(iv)(H) to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(BB) QCDR Measure Addresses a Measurement Gap

As a part of the QCDR measure development process, QCDRs should conduct an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy program, PQRS; and review the most recent CMS Quality Measure Development Plan Annual Report, which is currently available for 2019 at: *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2019-Quality-MDP-Annual-Report-and-Appendices.zip* and the Blueprint for the CMS Measures Management System: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* for guidance in areas where CMS has identified gaps in quality measurement to reduce the possibility of duplicative measure development. We propose to amend § 414.1400 to add § 414.1400(b)(3)(iv)(I) to state that we would give greater consideration to measures for which QCDRs: (a) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and (b) utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.

(CC) QCDRs Measures Meeting Benchmarking Thresholds

Over the first 2 years of MIPS, we have observed instances where QCDR measures have been approved for continued use in the program, but have had low reporting volumes, below the case minimum and reporting volume thresholds required for a measure to be benchmarked within the program. As described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77282), for benchmarks to be developed, a measure must have a minimum of 20 individual clinicians or groups who reported the measure to meet the data completeness requirement and the minimum case size criteria. QCDRs should be aware of which measures are considered low-reported, since measures that do not meet benchmarking thresholds result in a 3-point floor, as described in the CY 2017 Quality Payment Program final rule (81 FR 77282). QCDR measures are reviewed and approved on an annual

basis, and as a part of the review process, we review: The benchmarking file from the previous year (for example, the 2019 Quality Benchmark file, found on the QPP Resource Library, which is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip*); production submission data submitted from the previous year's data submission period; and data provided to us by the QCDRs themselves.

As discussed in our QCDR measure rejection considerations proposal below, we propose a QCDR measure that does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance may not continue to be approved in the future if our proposal is finalized as proposed. We note that this factor is parallel to what is being proposed for MIPS quality measures in section III.K.3.c.(1) of this proposed rule, and is important when considering the volume of QCDR measures that are currently in the program that have had low reporting rates year-over-year. We propose to amend § 414.1400 to add paragraph (b)(3)(iv)(J) to state that beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved. We refer readers to section III.K.3.g.(3)(c)(ii) below in this proposed rule, for discussion on how QCDRs may create participation plans for existing approved QCDR measures that have failed to reach benchmarking thresholds, in order to be reconsidered for future use. We also refer readers to § 414.1330 for additional information.

(B) QCDR Measure Requirements

(aa) Previously Finalized Requirements Considerations Codified as Requirements

As mentioned above, in this proposed rule, we propose to change two previously finalized measure considerations into requirements and codify those requirements. We previously finalized that we would apply certain criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS (83 FR 59902). We refer readers to section III.K.3.g.(3)(c)(i)(A) where we are proposing to codify the majority as measure considerations. However, for two of those previously finalized consideration, we are proposing them as requirements:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

We believe the previously finalized consideration that measures are beyond the measure concept phase of development should be a requirement because measures that do not surpass the measure concept phase will not be able to complete another QCDR measure requirement, measure testing. In addition, we believe the previously finalized consideration that measures address significant variation in performance should be a requirement because QCDR measures that do not demonstrate performance variation will likely be identified as topped out and will not be approved.

Therefore, beginning with the 2020 performance period, we are proposing to change both of those considerations into requirements and are proposing to amend § 414.1400 by adding § 414.1400(b)(3)(v) to include the following:

- Measures that are beyond the measure concept phase of development.
- Measures that address significant variation in performance.

(bb) Linking QCDR Measures to Cost Measures, Improvement Activities, and MIPS Value Pathways (MVP)

To prepare QCDR measures for self-nomination, we believe there should be consideration of how these QCDR measures relate to similar topics covered through the other performance categories. We believe (as noted in the Transforming MIPS: MIPS Value Pathways Framework, *see* section III.K.3.a. of this proposed rule) that to transform the MIPS program to one of value, MIPS measures and QCDR measures, should have an associated cost measure, improvement activity, and eventually a corresponding MVP. This would strengthen the QCDR measure's relevance in the program. We believe that evaluating the strength of these linkages may decrease the frequency of receiving extraneous QCDR measures that are not relevant or meaningful within the framework of the MIPS program.

Therefore, beginning with the 2021 performance period and future years, we propose that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measure (as found in section III.K.3.c.(2) of this proposed rule); (b) Improvement Activity (as found in Appendix 2: Improvement Activities Tables); or (c) CMS developed MVPs (as described in Table C–B1 of section III.K.3.a. of this proposed rule). Under the pathway framework for example, a surgery specific QCDR should be able to correlate their surgery-related QCDR measure to an MVP, such as the Major Surgery pathway.

We understand that not all measures may have a direct link. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements defined above.

However, we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities. Therefore, we also propose to amend § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures to the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; and (c) an MVP. If the potential QCDR measure otherwise meets the QCDR measure requirements but does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions for measures that otherwise meet the QCDR measure requirements and considerations as discussed above.

Therefore, we also propose to amend § 414.1400 to add paragraph (b)(3)(iv)(G) to require, beginning with the 2021 performance period, that QCDRs link their QCDR measures to the following at the time of self-nomination: (a) Cost measure; (b) improvement activity; and (c) an MVP. In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements.

(cc) Completion of QCDR Measure Testing

We refer readers to the CY 2019 PFS final rule, where we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). After consideration of the public comments received, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we are moving forward with a proposal in this proposed rule.

Beginning with the 2021 performance period and future years, we propose,

that for a QCDR measure to be considered for use in the program, all QCDR measures submitted at the time of self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), and as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. We believe that full development and testing with completed testing results at the clinician level helps to demonstrate whether the QCDR measure is ready for implementation at the time of self-nomination. We intend to include only measures that are valid, reliable, and feasible for use by clinicians and will be consistent with the criteria that is expected of MIPS quality measures. As a result, we are also proposing to amend § 414.1400 to add paragraph (b)(3)(v)(C) to reflect this proposal. At § 414.1400(b)(3)(v)(C), we propose beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

We note that the testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type. Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported.[137] While we understand the proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval while others do not. This variability makes it difficult to estimate the incremental impact of this regulation. Please refer to section VI the Regulatory Impact Analysis of this rule for additional details.

(dd) Collection of Data on QCDR Measures

We have observed several instances in which QCDRs have attempted to use the MIPS Program to ''test'' out measure concepts without concrete evidence that there is a measurement performance gap. We want to discourage that and ensure QCDR measures used for the MIPS Program are valid and reliable. In addition, through reviews of QCDR measure submissions, where reporting data was provided by the QCDR or through submission data from the 2017 performance period, we have identified some current QCDR measures in the program that have continuously low reporting rates, which affects the ability to meet benchmarking criteria. The data submitted is insufficient in meeting the case minimum and volume thresholds required for benchmarking.

Therefore, we are proposing to require QCDRs to collect data on the potential QCDR measure. For a QCDR measure to be considered for use in the program, beginning with the 2021 performance period and future years, we are proposing to amend § 414.1400 to add paragraph (b)(3)(v)(D) that QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. The data collected must demonstrate whether the QCDR measure is valid and reflects an important clinical concept(s) that clinicians wish to be measured on. By collecting data on the QCDR measure prior to self-nomination, QCDRs would be able to demonstrate whether the measure is implementable and data collection on the metric is possible. In addition, the data collected on the QCDR measure prior to self-nomination, could be used to demonstrate that there is a performance gap and need for measurement. We suggest QCDRs to collect data on as many months as possible, but strongly encourage QCDRs to collect data for 12 months prior to submitting the QCDR measure for our consideration at the time of self-nomination, since quality reporting requires 12 months of data, as described in § 414.1335, as this will also likely increase the chance that the measure will be able to be benchmarked.

(ee) Duplicative QCDR Measures

As first discussed by commenters in the CY 2018 Quality Payment Program final rule (82 FR 53814), the topic of ''shared'' measures was discussed and how would CMS intend to harmonize. In the CY 2019 PFS proposed rule (83 FR 35983), and further discussed in CY 2019 PFS final rule (83 FR 59901), we shared that we believe duplicative measures are counterintuitive to the Meaningful Measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. Therefore, it is our intent to move toward measure harmonization, which supports our efforts to increase measure alignment and eliminate redundancy both within the MIPS measure set and across our programs (83 FR 59901). Taking the previous feedback into consideration, we are moving forward with a proposal in this rule.

Therefore, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. In other words, we would not approve duplicative QCDR measures (which will be identified as a part of our scan of previously approved measures, and new QCDR measure submissions) if QCDRs choose not to address the areas of duplication with other approved QCDR measures identified by us during the previous year's QCDR measure review period. We believe this policy would help to reduce the number of duplicative QCDR measures that are submitted as a part of the self-nomination process. Adding a structured timeframe provides

[137] Schuster, Onorato, and Meltzer. ''Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy'', Journal of the American Medical Association. 2017; 318(13):1219–1220. *https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1.*

transparency to QCDRs who will know what next steps to expect if they do not address the identified areas of duplication as requested. Therefore, we propose to amend § 414.1400 to add paragraph (b)(3)(v)(E) to state beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure(s) as discussed in section III.K.3.g.(3)(c)(i)(C) below.

(C) QCDR Measure Rejections

We are proposing QCDR measure rejection criteria that generally aligns with finalized removal criteria for MIPS quality measures in the CY 2019 PFS final rule (83 FR 59763 through 59765). Utilizing these considerations would help to ensure that QCDR measures available in the program are truly meaningful and measurable areas where quality improvement is sought. As part of this proposal, all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program.

We propose to amend § 414.1400 to add paragraph (b)(3)(vii) to state that beginning with the 2020 performance period, we propose to reject QCDR measures with consideration of, but not limited to, the following factors:

- QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.
- QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.
- QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.
- QCDR measures that meet the ''topped out'' definition as described at § 414.1305 and in the CY 2017 QPP final rule (81 FR 77282 through 77283). If a QCDR measure is topped out and rejected, it may be reconsidered for the program in future years if the QCDR can provide evidence through additional data and/or recent literature that a performance gap exists and show that the measure is no longer topped out during the next QCDR measure self-nomination process.
- QCDR measures that are process-based, with considerations to whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the QCDR measure has potential unintended consequences to a patient's care. For example, the measure disqualifies a patient from receiving oxygen therapy or other comfort measures.
- Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.
- Whether the previously identified areas of duplication have been addressed as requested. (We refer readers to our proposal discussed in section III.K.3.g.(3)(c)(i)(B) above.)
- QCDR measures that split a single clinical practice or action into several QCDR measures. For example, splitting a measure into multiple measures based on a particular body extremity: Improvement in toe pain—the 5th toe, and a separate measure for the 2nd toe.
- QCDR measures that are ''check-box'' with no actionable quality action. For example, a QCDR measure that measures that a survey has been distributed to patients.
- QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years (we also refer readers to our proposal in section III.K.3.g.(3)(c)(ii) below).
- Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality action, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.
- QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician (that is, the quality aspect being measured cannot be attributed to the clinician or is not under the direct control of the reporting clinician).
- QCDR measures that focus on rare events or ''never events'' in the measurement period. An example of a ''never event'' would be a fire in the operating room.

(ii) QCDR Measure Review Process

(A) Current QCDR Measure Approval Process

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), and the CY 2019 PFS final rule (83 FR 59900 through 59906), and § 414.1400(b)(3) for our previously established policies for the QCDR measure self-nomination process. QCDR measures are reviewed for inclusion on an annual basis during the QCDR measure review process that occurs once the self-nomination period closes (82 FR 53810). All previously approved QCDR measures and new QCDR measures are currently reviewed on an annual basis to determine whether they are appropriate for the program (82 FR 53811). The QCDR measure review process occurs after the self-nomination period closes on September 1st. QCDR measures are not finalized or removed through notice and comment rulemaking; instead, they are currently approved or not approved through a subregulatory processes (82 FR 53639). While we would continue to review measures on an annual basis, in this proposed rule, we are proposing the addition of a multi-year approval process.

(B) Multi-Year QCDR Measure Approval

Previously in the CY 2018 Quality Payment Program final rule (82 FR 53808), we discussed our concerns with multi-year approval for QCDR measures and sought comment from stakeholders as to how to mitigate our concerns. Based on the evolution of public comments in the CY 2019 PFS final rule (83 FR 59898 through 59901) and ongoing engagement with QCDRs, we are moving forward with a proposal in this rule.

Currently, our QCDR measure approvals are on a year-to-year basis (82 FR 53811), from September to December once self-nomination occurs. In addition to that process, to help reduce yearly self-nomination burden and address stakeholder feedback (83 FR 59898 through 59901), we are proposing to amend § 414.1400 to add paragraph (b)(3)(vi) to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described above.

However, as part of this proposal, upon annual review, we may revoke the second year's approval if a QCDR measure approved for 2 years is:

- Topped out (we refer readers to § 414.1305, in the CY 2017 QPP final rule (81 FR 77282 through 77283));
- Duplicative of a more robust measure (this proposal aligns with our

proposal at section III.K.3.g.(3)(c) above);

- Reflects an outdated clinical guideline;
- Requires measure harmonization (this proposal aligns with our proposal at section III.K.3.g.(3)(c)(i)(B) above); or
- The QCDR self-nominating the QCDR measure is no longer in good standing, as described in the CY 2018 Quality Payment Program final rule (82 FR 53808).

We believe that this policy should be an incentive for QCDRs who have remained in good standing in the program. Additionally, for QCDRs not in good standing, we want to make clear that we would not remove a measure mid-year; rather, the measure's 2-year approval would be revoked during annual review after 1 year and the QCDR's measures would no longer qualify for multi-year approval in the future. For example, if QCDR ABC is placed on probation in July, all of the QCDR's measures still would be available for reporting for that performance period (until December 31st); however, if any of QCDR ABC's QCDR measures were previously approved for 2 years, the approval would be revoked for the second year.

(iii) Participation Plan for Existing QCDR Measures That Have Failed To Reach Benchmarking Thresholds

We refer readers to section III.K.3.g.(3)(c)(i), above in this proposed rule for discussion of the consideration of QCDR measures that fail to meet benchmarking thresholds after being in the program for 2 consecutive CY performance may not continue to be approved in the future.

However, we understand that there are instances where measures that are low-reported may still be considered important to a respective specialty. Therefore, beginning with the 2020 performance period, we propose to amend § 414.1400 to add paragraph (b)(3)(iv)(J)(aa) to state in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program. As examples, a QCDR measure participation plan could include one or more of the following:

- Development of an education and communication plan.
- Update the QCDR measure's specification with changes to encourage broader participation, which would require review and approval by us.
- Require reporting on the QCDR measure as a condition of reporting through the QCDR.

To be clear, implementation of a participation plan would not guarantee that a QCDR measure would be approved for a future performance period, as we consider many factors in whether to approve QCDR measures. At the following annual review of QCDR measures, we would analyze the measure's data submissions to determine whether the QCDR measure participation plan was effective (meaning, reporting volume increased, thereby increasing the likelihood of the QCDR measure being benchmarked). If the data does not show an increase in reporting volume, we may not approve the QCDR measure for the subsequent year.

(4) Qualified Registries

We refer readers to §§ 414.1305 and 414.1400, the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) and the CY 2019 PFS final rule proposed rule (83 FR 59906) for our previously finalized policies regarding qualified registries. In this proposed rule, we propose to update qualified registry required services. These proposals would also affect the qualified registry self-nomination process.

(a) Qualified Registry Required Services

(i) Requirement for Qualified Registries To Support All Three Performance Categories Where Data Submission Is Required

We refer readers to section 1848(k)(4) of Act for statutory authority. We also refer readers to section III.K.3.g.(3) above, where we propose to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In addition, we refer readers to section III.K.3.g.(3)(a)(i) where we discuss a parallel requirement for QCDRs. In this section, we discuss qualified registries specifically. Based on previously finalized policies the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088) and § 414.1400(a)(2), the current policy is that QCDRs, qualified registries, and health IT vendors may submit data for any of the following MIPS performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability.

We want to continue to strengthen our policies at § 414.1400(a)(2). Based on our review of existing 2019 qualified registries, approximately 95 qualified registries, or about 70 percent of the qualified registries currently participating in the program are supporting all three performance categories. The qualified posting of approved 2019 qualified registries can be found on the QPP resource library at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/348/2019%20Qualified%20Registry%20Posting_Final_v1.0.xlsx*. We believe it is reasonable that all qualified registries have the capacity to support the improvement activities and promoting interoperability performance categories.

We believe that requiring qualified registries to be able to support these performance categories will be a step towards addressing stakeholders concerns on having a more cohesive participation experience across all performance categories under MIPS. In addition, we believe this proposal will help to reduce the reporting burden MIPS eligible clinicians and groups face when having to utilize multiple submission mechanisms to meet the reporting requirements of the various performance categories. Furthermore, as we move to a more cohesive participation experience under the MVPs, as discussed in section III.K.3.a. of this proposed rule, Transforming MIPS Path to Value, we believe this proposal will assist clinicians in that transition.

Therefore, as discussed above beginning with the 2021 performance period and for future years, we propose at § 414.1400(a)(2) to require qualified registries to support all three performance categories: Quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability with an exception. As discussed in section III.K.3.g.(1) of this rule, we are proposing that based on the proposed amendment to § 414.1400(a)(2)(iii), to state that for the Promoting Interoperability performance category, the requirement applies if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(4), (c)(2)(i)(A)(5), (c)(2)(i)(C)(1) through (c)(2)(i)(C)(7), or (c)(2)(i)(C)(9). As part of this proposal, we would require qualified registries to attest to the ability to submit data for

these performance categories, as applicable, at time of self-nomination. We are also proposing this same requirement for QCDRs in section III.K.3.g.(3) of this proposed rule.

(ii) Enhanced Performance Feedback Requirement

Section 1848(q)(12)(A)(ii) of the Act requires the Secretary to encourage the provision of performance feedback through qualified registries. In addition, in establishing the requirements, the Secretary must consider, among other things, whether an entity ''provides timely performance reports to participants at the individual participant level''. Currently, CMS requires qualified registries to provide feedback on all of the MIPS performance categories at least 4 times per year (81 FR 77367 through 77386). While based on our experiences thus far during the initial years of the Quality Payment Program, we agree that providing feedback at least 4 times a year is appropriate. However, in the future CMS would like to see, and therefore encourages qualified registries, to provide timely feedback on a more frequent basis more than 4 times a year. Receipt of more frequent feedback will help clinicians and groups make more timely changes to their practice to ensure the highest quality of care is being provided to patients. We see value in providing more timely feedback to meet the objectives [138] of the Quality Payment Program in improving the care received by Medicare beneficiaries, lowering the costs to the Medicare program through improvement of care and health, and advance the use of healthcare information between allied providers and patients. We also believe there is value in this performance feedback and therefore encourage qualified registries to work with their clinicians to get the data in earlier in the reporting period so the qualified registry give that meaningful timely feedback.

Surrounding the qualified registry performance feedback provided to clinicians and groups, we have heard from stakeholders that not all qualified registries provide feedback the same way. We have heard through stakeholder comments some qualified registries feedback contains information needed to improve quality, whereas other qualified registries feedback does not supply such information due to the data collection timeline. Additionally, we believe that clinicians would benefit from feedback on how they compare to other clinicians who have submitted data on a given MIPS quality measure within the qualified registry they are reporting through, so they can identify areas of measurement in which improvement is needed, and furthermore they can see how they compare to their peers based within a qualified registry, since the feedback provided by the qualified registry would be limited to those who reported on a given measure using that specific qualified registry.

As a result, we are proposing to add a new paragraph at § 414.1400(c)(2) to require (i) and (ii). We are simply proposing to revise the current § 414.1400(c)(2) to reclassify at paragraph (c)(2)(i) that beginning with the 2022 MIPS payment year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. Additionally, we are proposing to add a new paragraph, § 414.1400(c)(2)(ii), beginning with the 2023 MIPS payment year, to require that qualifed registries provide the following as a part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. We understand that there would be instances in which the qualified registry cannot meet this requirement; and therefore, we are also proposing an exception to this requirement: If the qualified registry does not receive the data from their clinician until the end of the performance period, this will preclude the qualified registry from providing feedback 4 times a year, and the qualified registry could be excepted from this requirement. We are also soliciting comment on other exceptions that may be necessary under this requirement.

We also understand that qualified registries can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the qualified registry does not have access to. We believe qualified registry internal comparisons can still help MIPS eligible clinicians identify areas where further improvement is needed. The ability for MIPS eligible clinicians to be able to know in real time how they are performing against their peers, within a qualified registry, provides immediate actionable feedback.

Furthermore, we are also proposing to strengthen the qualified registry self-nomination process at § 414.1400(c)(1) to add that beginning with the 2023 MIPS payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)). We refer readers to section III.K.3.g.(3)(1) where we are proposing a parallel requirement for QCDRs; we intend to have the same requirements for both QCDRs and qualifies registries.

In addition, the current performance period begins January 1 and ends on December 31st, and the corresponding data submission deadline is typically March 31st as described at § 414.1325(e)(1). As discussed above, we have heard from qualified registry stakeholders that in some instances clinicians wait until the end of the performance period to submit data to the third party intermediary, who are then unable to provide meaningful feedback to their clinicians 4 times a year. Therefore, we are also seeking comment for future notice-and-comment rulemaking on whether we should require MIPS eligible clinicians, groups, and virtual groups who utilize a qualfied registry to submit data throughout the performance period, and prior to the close of the performance period (that is, December 31st). We are also seeking comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the qualified registry is providing feedback and the clinician or group during the performance period. This would allow qualified registries some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline.

(5) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548) and the CY 2019 PFS final rule (83 FR 59908 through 59910) for previously finalized policies for remedial action and termination of third party intermediaries.

Based on experience with third party intermediaries thus far, we have concerns that certain third party intermediaries may not fully appreciate their existing compliance obligations or the implications of non-compliance. Among other provisions, § 414.1400(a)(5) specifically obligates each third party intermediary to certify that all data it submits to CMS on behalf of a MIPS eligible clinician, group or virtual group is true, accurate and complete to the best of its knowledge.

[138] Quality Payment Program Overview. *https://qpp.cms.gov/about/qpp-overview.*

Section 414.1400(f)(1) states that, after providing written notice, CMS may take remedial action or terminate a third party intermediary if CMS determines that the third party intermediary has ceased to meet one or more of the applicable criteria for approval or has submitted data that is inaccurate, unusable or otherwise compromised. Moreover, § 414.1400(f)(3) identifies specific circumstances under which CMS may determine that data submitted by a third party intermediary meets the standard for inaccurate, unusable or otherwise compromised data.

Third parties intermediaries have an affirmative obligation to certify that the data they submit on behalf of a MIPS eligible clinician, group or virtual group are true, accurate and complete to the best of its knowledge. MIPS data that are inaccurate, incomplete, unusable or otherwise compromised can result in improper payment. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period, commonly referred to as ''cherry-picking,'' results in data submissions that are not true, accurate or complete. A third party intermediary cannot certify that data submitted to CMS by the third party intermediary are true, accurate and complete to the best of its knowledge if the third party intermediary knows the data submitted are not representative of the clinician's or group's performance. As described in section III.K.3.c.(1) of this proposed rule, we proposed to further amend § 414.1340(a)(3) to clarify that the submitted data should be reflective of a 70 percent random sample. We believe this clarification will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance. Accordingly, a third party intermediary that submits a certification under § 414.1400(a)(5) in connection with the submission of data it knows are cherry-picked has submitted a false certification in violation of existing regulatory requirements. If CMS believes cherry-picking of data may be occurring, we may subject the third party intermediary and its clients to auditing in accordance with § 414.1400(g).

Despite these existing obligations, we have received inquiries from third party intermediaries regarding perceived opportunities to selectively submit data that are unrepresentative of the MIPS performance of the clinician or group for which the third party intermediary is submitting data. These inquires suggest that certain third party intermediaries may not fully appreciate their current regulatory obligations or their implications.

The current regulations at § 414.1400(f) clearly establish that CMS enforcement authority includes the authority to pursue remedial actions or termination based on its determination that a third party intermediary was non-compliant with any applicable criteria for approval in § 414.1400(a) through (e) or if the third party intermediary submitted data that are inaccurate, unusable or otherwise compromised. Compliance within § 414.1400(a)(5) is a criteria for approval. Using data selection criteria to misrepresent a clinician or group's performance for an applicable performance period results in data that are inaccurate, unusable and otherwise compromised. Accordingly, if CMS determined that third party intermediary knowingly submitted data that are not representative of the clinician's or group's performance and certified that the submitted data were true, accurate and complete, CMS would have multiple grounds to impose remedial action or termination under existing regulations.

In this proposed rule, we propose two changes to more expressly emphasize CMS enforcement authority. First, we propose to clarify in this proposed rule that remedial action and termination provisions at § 414.1400(f)(1) are triggered if we determine that a third party intermediary submits a false certification under paragraph (a)(5). Second, as discussed below, we propose to clarify in this proposed rule that CMS authority to bring remedial actions or terminate a third party intermediary for submitting data that is inaccurate, unusable or otherwise compromise extends beyond the specific examples set forth in § 414.1400(f)(3). With these revisions and a grammatical correction described below, the proposed § 414.1400(f)(1) would affirm existing CMS authority to purse remedial actions or termination if we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, submits a false certification under paragraph (a)(5), or has submitted data that are inaccurate, incomplete, unusable, or otherwise compromised. We anticipate that these proposed revisions will emphasize to third party intermediaries the sanctions they may face from CMS if they submit improper data to CMS. In addition, we note that third party intermediaries may face liability under the federal False Claims Act if they submit or cause to submission of false MIPS data.

As noted above, we are proposing revisions to § 414.1400(f)(3) to clarify the intent of this provision. We refer readers to CY 2019 PFS final rule (83 FR 59908 through 59910) for the discussion of the evolution of policies regarding remedial actions and termination of a third party intermediary. The agency's enforcement authority as codified in § 414.1400(f) broadly extends to include instances of willful misconduct by the third party intermediary and well as other instances in which a third party intermediary inadvertently submits data with deficiencies and errors that render the data ''inaccurate, unusable or otherwise compromised.'' To facilitate a more fulsome understanding on when inadvertent conduct could trigger an enforcement action against a third party intermediary, the current regulatory text in § 414.1400(f)(3) provides that the threshold for ''inaccurate, unusable or otherwise compromised'' may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible clinicians or groups for which data was submitted by the third party intermediary. Through this proposed rule, we propose to add the phrase ''including but not limited to'' to the text of § 414.1400(f)(3) to emphasize that this provision is illustrative of circumstances that may result in enforcement action and should not be misinterpreted to limit the agency's ability to impose remedial actions or terminate a third party intermediary that knowingly submits inaccurate data.

Lastly, we propose grammatically corrections related to the use of the plural term ''data.''

h. Public Reporting on Physician Compare

(1) Background

For previous discussions on the background of Physician Compare, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), and the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

We are proposing to publicly report on Physician Compare: (1) Aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY

2019), as technically feasible; and (2) an indicator on the profile page or in the downloadable database that displays if a MIPS eligible clinicians is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible. These proposals are discussed in more detail in this proposed rule.

(2) Regulation Text Changes

Section 1848(q)(9)(A) and (D) of the Act requires that we publicly report on Physician Compare in an easily understandable format:

- The final score for each MIPS eligible clinician;
- Performance of each MIPS eligible clinician for each performance category;
- Periodic aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category;
- The names of eligible clinicians in advanced APMs and, to the extent feasible, the names of such advanced APMs and the performance of such APMs.

Section 1848(q)(9)(B) of the Act requires that the information made available under section 1848(q)(9) of the Act must indicate, where appropriate, that publicized information may not be representative of the eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

To more completely and accurately reference the data available for public reporting on Physician Compare, we propose to amend § 414.1395(a) by adding paragraph (1) stating that CMS posts on Physician Compare, in an easily understandable format: (i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and (ii) the names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs. As discussed in section III.K.3.h.(3) of this proposed rule, we are also proposing to amend § 414.1395(a) by adding paragraph (2) stating that CMS periodically posts on Physician Compare aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. Finally, we propose to amend § 414.1395(a) by adding paragraph (3) stating that the information made available under § 414.1395 will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

(3) Final Score, Performance Categories, and Aggregate Information

Section 1848(q)(9)(D) of the Act requires the Secretary to periodically post on Physician Compare aggregate information on the MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53823), where we previously finalized policies to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years.

Although we previously finalized a policy to periodically post aggregate information on the MIPS, as technically feasible, for all future years, we have not proposed or finalized in rulemaking a specific timeframe for doing so. As part of our phased approach to public reporting, we wanted to first gain experience with the MIPS data prior to publicly reporting it in aggregate, since we had not publicly reported on Physician Compare aggregate data under legacy programs. For example, we publicly reported the Physician Quality Reporting System (PQRS) performance information only at an individual clinician and group practice level. Now that we have experience with the MIPS data, including the Year 1 performance information which was not available for analysis at the time of prior rulemaking, we can now propose a specific timeframe for publicly reporting aggregate MIPS data on Physician Compare.

Therefore, in accordance with section 1848(q)(9)(D) of the Act, we propose to publicly report on Physician Compare aggregate MIPS data, including the minimum and maximum MIPS performance category and final scores earned by MIPS eligible clinicians, beginning with Year 2 (CY 2018 data, available starting in late CY 2019), as technically feasible, and to codify this proposed policy at § 414.1395(a). We wish to clarify that the aggregate data publicly reported would be inclusive of all MIPS eligible clinicians. We also note that some aggregate MIPS data is already publicly available in other places, such as via the Quality Payment Program Experience Report. We note that the 2017 Quality Payment Program Experience Report is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/491/2017%20QPP%20Experience%20Report.pdf*. As noted in the CY 2018 Quality Payment Program final rule (82 FR 53823), we will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel, to determine how and where these data are best reported on Physician Compare (for example in the Physician Compare Downloadable Database or on the Physician Compare Initiative page). In addition to minimum and maximum MIPS performance category and final scores, we also seek comment on any other aggregate information that stakeholders would find useful for future public reporting on Physician Compare.

(4) Quality

For previous discussions on publicly reporting quality performance category information on the Physician Compare website, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53824) and the CY 2019 Quality Payment Program final rule (83 FR 59912).

Although we are not making any proposals regarding publicly reporting quality performance category information, we are seeking additional comments on adding patient narratives to the Physician Compare website in future rulemaking, to the extent consistent with our authority to collect such information under section 1848(q) of the Act and our authority to include an assessment of patient experience and patient, caregiver, and family engagement under section 10331(a)(2)(E) of the Affordable Care Act. Physician Compare website user testing has repeatedly shown that Medicare patients and caregivers greatly desire narrative reviews, quotes and testimonials by their peers, and a single overall ''value indicator,'' reflective for each MIPS eligible clinician and group, and would expect to find such information on the Physician Compare website already, based on their experiences with other consumer-oriented websites. We currently do not

display any narrative patient satisfaction information on Physician Compare or any single overall value indicator for MIPS eligible clinicians and groups (except MIPS performance category and final scores); currently all performance information on Physician Compare is publicly reported at the individual measure level. Therefore, we are seeking comment on the value of and considerations for publicly reporting such information to assist patients and caregivers with making healthcare decisions, building upon the feedback received in response to the CY 2018 Quality Payment Program proposed rule (82 FR 30166 through 30167), in which we specifically sought comment on publicly reporting responses to five open-ended questions that are part of the Agency for Healthcare Research and Quality (AHRQ)'s CAHPS Patient Narrative Elicitation Protocol (*https://www.ahrq.gov/cahps/surveys-guidance/item-sets/elicitation/index.html*). We refer readers to section III.K.3.c.(1)(c)(i) of this proposed rule for an additional solicitation for comments to add narrative reviews into the CAHPS for MIPS group survey in future rulemaking.

To be publicly reported on Physician Compare, patient narrative data would have to meet our public reporting standards, described at § 414.1395(b), and reviewed in consultation with the Physician Compare Technical Expert Panel, to determine how and where these data would be best reported on Physician Compare. We seek comment on the value of collecting and publicly reporting information from narrative questions and other PROMs, as well as publishing a single ''value indicator'' reflective of cost, quality and patient experience and satisfaction with care for each MIPS eligible clinician and group, on the Physician Compare website and will consider feedback from the patient, caregiver, and clinician communities before proposing any policies in future rulemaking. We also note that if we propose to publicly report patient narratives in future rulemaking, we will address all related patient privacy safeguards consistent with section 10331(c) of the Affordable Care Act, which requires that information on physician performance and patient experience is not disclosed in a manner that violates the Freedom of Information Act (5 U.S.C. 552) or the Privacy Act of 1974 (5 U.S.C. 552a) with regard to the privacy individually identifiable health information, and other applicable law.

(5) Promoting Interoperability

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53827) and the CY 2019 Quality Payment Program final rule (83 FR 59913) for previously finalized policies related to the Promoting Interoperability performance category and Physician Compare.

Although we are not making any proposals regarding publicly reporting Promoting Interoperability category information, we do want to refer readers to the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers'' proposed rule (referred to as the Interoperability and Patient Access proposed rule) published in the March 4, 2019 **Federal Register** (84 FR 7646 through 7647), where we proposed to include an indicator on Physician Compare for the eligible clinicians and groups that submit a ''no'' response to any of the three prevention of information blocking attestation statements in § 414.1375(b)(3)(ii)(A) through (C). To report successfully on the Promoting Interoperability performance category, in addition to satisfying other requirements, a MIPS eligible clinician must submit an attestation response of ''yes'' for each of these statements. These statements contain specific representations about a clinician's implementation and use of CEHRT and are intended to verify that a MIPS eligible clinician has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology. In the event that these statements are left blank, that is, a ''yes'' or a ''no'' response is not submitted, the attestations would be considered incomplete, and we would not include an indicator on Physician Compare. We also proposed to post this indicator on Physician Compare, either on the profile pages or the downloadable database, as feasible and appropriate, starting with the 2019 performance period data available for public reporting starting in late 2020. We refer readers to the CY 2017 Quality Payment Program final rule for additional information on these attestation statements (81 FR 77028 through 77035).

We note that addressing comments on this proposed policy is outside of the scope of this proposed rule and instead direct readers to review that proposed rule, available at *https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and*, for more information.

(6) Facility-Based Clinician Indicator

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy to publicly report the MIPS performance category and final scores earned by each MIPS eligible clinician on Physician Compare, either on profile pages or in the downloadable database. We also finalized that we will make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible (82 FR 53824). We will use statistical testing and user testing to determine how and where measures are reported on Physician Compare. We established at § 414.1380(e) a facility-based measurement scoring option under the MIPS quality and cost performance categories for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year. Section 414.1380(e)(1)(ii) provides that the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

With this in mind, we have considered how to best display facility-based MIPS eligible clinician quality and cost information on Physician Compare, appreciating our obligation to publicly report certain MIPS data for MIPS eligible clinicians and groups. As those clinicians and groups scored under the facility-based option are MIPS eligible, we will publicly report their performance category and MIPS final scores on Physician Compare and considered two options for publicly reporting their facility-based measure-level performance information on Physician Compare: (a) Displaying hospital-based measure-level performance information on Physician Compare profile pages, including scores for specific measures and the hospital overall rating; or (b) including an indicator showing that the clinician or group was scored using the facility-based scoring option with a link from the clinician's Physician Compare profile page to the relevant hospital's

measure-level performance information on Hospital Compare. We believe that a link from the clinician's Physician Compare profile page to the relevant hospital's performance information on Hospital Compare is preferable for several reasons including: Concerns about duplication with Hospital Compare, interpretability by Physician Compare website users expecting to find clinician-level, rather than hospital-level, information and operational feasibility. Additionally, we believe this approach is consistent with our consumer testing findings that Medicare patients and caregivers find value in information on the relationships clinicians and groups may have with facilities where they perform services. We note that the facility-based scoring indicator would be separate from the hospital affiliation information for admitting privileges currently posted on Physician Compare profile pages.

For these reasons, we are proposing to make available for public reporting an indicator on the Physician Compare profile page or downloadable database that displays if a MIPS eligible clinician is scored using facility-based measurement, as specified under § 414.1380(e)(6)(vi), as technically feasible. We are also proposing to provide a link to facility-based measure-level information, as specified under § 414.1380(e)(1)(i), for such MIPS eligible clinicians on Hospital Compare, as technically feasible. In addition, we are proposing to post this indicator on Physician Compare with the linkage to Hospital Compare beginning with CY 2019 performance period data available for public reporting starting in late CY 2020 and for all future years, as technically feasible. We request comment on this proposal.

4. Overview of the APM Incentive

a. Overview

Section 1833(z) of the Act requires that an incentive payment be made in years 2019 through 2024 (or, in years after 2025, a different PFS update) to Qualifying APM Participants (QPs) for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in payment year 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.
- For payment years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered professional services. Beginning in payment year 2026, QPs receive a higher update under the PFS for the year than non-QPs.
- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Medicare Advanced APMs.
- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Medicare Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to Advanced APMs, QP and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and Physician-Focused Payment Models (PFPMs).

In the CY 2019 PFS final rule (83 FR 59915 through 59940), we finalized clarifications, modifications, and additional details pertaining to use of Certified Electronic Health Record Technology (CEHRT), MIPS-comparable quality measures, bearing financial risk for monetary losses, the QP Performance Period, Partial QP election to report to MIPS, Other Payer Advanced APM criteria, determination of Other Payer Advanced APMs, calculation of All-Payer Combination Option Threshold Scores and QP determinations under the All-Payer Combination Option.

In this proposed rule, we discuss proposals pertaining to Advanced APMs and the All-Payer Combination Option.

b. Terms and Definitions

As we continue to develop the Quality Payment Program, we have identified the need to propose new definitions to go along with the previously defined terms. A list of the previously defined terms is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540), the CY 2018 Quality Payment Program final rule (82 FR 53951 through 53952), and in the CY 2019 PFS final rule (83 FR 60075 through 60076), and reflected in our regulation at § 414.1305.

In the CY 2017 Quality Payment Program final rule, we defined the term ''Medical Home Model'' and ''Medicaid Medical Home Model.'' Since defining these terms in the CY 2017 Quality Payment Program final rule, we have sought comment on whether or not to establish a similar definition to describe payment arrangements similar to Medical Home Models and Medicaid Medical Home Models that are operated by other payers (82 FR 30180).

As discussed in section III.I.4.d.(2)(a) of this proposed rule, we propose to add the defined term ''Aligned Other Payer Medical Home Model'' to § 414.1305, to mean a payment arrangement (not including a Medicaid payment arrangement) operated by an other payer that formally partners with CMS in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:

- The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;
- Empanelment of each patient to a primary clinician; and
- At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; Risk-stratified care management; Coordination of care across the medical neighborhood; Patient and caregiver engagement; Shared decision-making; and/or Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

c. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

• Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);

• Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and

• Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to the Advanced APM criteria, Qualifying APM Participant (QP) and Partial QP determinations, the Other Payer Advanced APM criteria, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and we discussed Physician-Focused Payment Models (PFPMs).

In the CY 2019 PFS final rule (83 FR 59915 through 59938), we finalized the following:

Use of CEHRT:

• We revised § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity, or, for APMs in which hospitals are the APM Entities, each hospital, use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures:

• We revised § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

• We revised § 414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses:

• We revised § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

In this section of the proposed rule, we address policies regarding several aspects of the Advanced APM criterion on bearing financial risk for monetary losses—specifically our proposal to amend the definition of expected expenditures, and our request for comment on whether certain items and services should be excluded from the capitation rate for our definition of full capitation arrangements.

(2) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77418), we divided the discussion of this criterion into two main topics: (1) What it means for an APM Entity to bear financial risk for monetary losses under an APM (which we refer to as either the generally applicable financial risk standard or Medical Home Model financial risk standard); and (2) what levels of risk we would consider to be in excess of a nominal amount (which we refer to as either the generally applicable nominal amount standard or the Medical Home Model nominal amount standard).

(b) Expected Expenditures

In the CY 2017 Quality Payment Program final rule (81 FR 77550), we established a definition of expected expenditures at § 414.1415(c)(5) to mean the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, 'expected expenditures' means the episode target price. We established this definition of expected expenditures for the purpose of applying the Advanced APM financial risk criterion to determine whether an APM meets the generally applicable nominal amount standard.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28305 through 28309), we proposed to measure three dimensions of risk under our generally applicable nominal amount standards: (1) Marginal risk, which refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (2) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (3) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM.

However, based on commenters' concerns regarding technical complexity, we did not finalize the marginal risk and MLR components of the generally applicable nominal standard under the Advanced APM criteria (81 FR 77427), but did finalize those additional elements of risk under the Other Payer Advanced APM criteria. We stated in the CY 2017 Quality Payment Program final rule (81 FR 77426) that the marginal risk and MLR components were not necessary to explicitly include in the generally applicable nominal amount standard for Advanced APMs because we are committed to creating Advanced APMs with strong financial risk designs that incorporate risk adjustment, benchmark methodologies, sufficient stop-loss amounts, and sufficient marginal risk; and that all APMs involving financial risk that we operate now or in the future would meet or exceed the proposed marginal risk and MLR requirements. In the CY 2017 Quality Payment Program proposed rule (81 FR 28306), we explained that to determine whether an APM satisfies the marginal risk component of the generally applicable nominal amount standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We proposed that we would require that this percentage exceed a required marginal risk percentage of 30 percent regardless of the amount by which actual expenditures exceeded expected expenditures. We believed that any marginal risk below 30 percent could create scenarios in which the total risk could be very high, but the average or likely risk for an APM Entity would actually be very low (81 FR 28306).

Our rationale for proposing the marginal risk requirement was that the inclusion of the marginal risk requirement would contribute to maintaining a more than nominal level of average or likely risk under an Advanced APM. We did not finalize the marginal risk requirement under the Advanced APM criteria because, as noted above, we believed that all Advanced APMs that we operate now or would potentially operate in the future would meet or exceed the previously proposed marginal risk and MLR requirements, and more importantly, we believed the total risk portion of the nominal amount standard alone was sufficient to ensure that the level of average or likely risk under an

Advanced APM would actually be more than nominal for participants.

However, based on our experience to date, we are concerned that the total risk portion of the benchmark-based nominal amount standard as currently constructed may not always be sufficient to ensure that the level of average or likely risk under an Advanced APM is actually more than nominal for participants. This is because the benchmark-based nominal amount standard at § 414.1415(c)(3)(i)(B) is dependent upon the definition of expected expenditures codified at § 414.1415(c)(5), where expected expenditures are defined as the beneficiary expenditures for which an APM Entity is responsible under an APM, and for episode payment models, the episode target price.

In our experience implementing the Quality Payment Program and considering the diversity of model designs, we now believe there is a need to amend the definition of expected expenditures to ensure there are more-than-nominal levels of average or likely risk under an Advanced APM that would meet the generally applicable benchmark-based nominal amount standard. For instance, an APM could have a sufficient total risk to meet the benchmark-based nominal amount standard and a sharing rate that results in adequate marginal risk if actual expenditures exceed expected expenditures. However, in that same APM, the level of expected expenditures reflected in the APM's benchmark or episode target price could be set in a manner that would substantially reduce the amount of loss the APM Entity would reasonably expect to incur.

For an APM to meet the generally applicable benchmark-based nominal amount standard, we believe there should be not only the potential for financial losses based on expenditures in excess of the benchmark as provided in § 415.1415(c)(3)(i)(B) of our regulations, but also a meaningful possibility that an APM Entity might exceed the benchmark. If the benchmark is set in such a way that it is extremely unlikely that participants would exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is essentially illusory.

Therefore, in § 414.1415(c)(5), we are proposing to amend the definition of expected expenditures. Specifically, we are proposing to define expected expenditure as, for the purposes of this section, the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the expected Medicare Parts A and B expenditures for a participant in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for Advanced APM determinations.

In general, expected expenditures are expressed as a dollar amount, and may be derived for a particular APM from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, we recognize expected expenditures under an APM often are risk-adjusted and trended forward, and may be adjusted to account for expenditure changes that are expected to occur as a result of APM participation. For the purpose of this proposed definition of expected expenditures, we would not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of the APM.

We believe that this proposed amendment would allow us to ensure that there are more-than-nominal amounts of average or likely risk under an APM that meets the generally applicable benchmark-based nominal amount standard. We believe that the proposed amended definition of expected expenditures, particularly by our not considering excess expenditures when determining whether an APM meets the benchmark-based nominal amount standard, would provide a more definite basis for us to assess whether an APM Entity would bear more than a nominal amount of financial risk for participants under the generally applicable benchmark-based nominal amount standard.

We are also proposing a similar amendment to the definition of expected expenditures applicable to the Other Payer Advanced APM criteria in section III.I.4.d.(2)(b)(i) of this proposed rule.

We seek comment on this proposal.

(c) Excluded Items and Services Under Full Capitation Arrangements

In the CY 2017 Quality Payment Program final rule (81 FR 74431), we finalized a capitation standard at § 414.1415(c)(6), which provides that a full capitation arrangement meets the Advanced APM financial risk criterion. We defined a capitation arrangement as a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. We clarified that arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program are not considered capitation arrangements for purposes of this definition.

In the CY 2019 PFS final rule (83 FR 59939), we made technical corrections to the Advanced APM financial risk capitation standard at § 414.1415(c)(6). These corrections clarified that our financial risk capitation standard applies only to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As we have begun to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, we have noticed that some payment arrangements that are submitted as capitation arrangements consistent with § 414.1420(d)(7) include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, and out-of-network emergency services. In reviewing these exclusion lists, we believe that it may be appropriate for CMS to allow certain capitation arrangements to be considered ''full'' capitation arrangements even if they categorically exclude certain items or services from payment through the capitation rate.

As such, we are seeking comment on what categories of items and services might be excluded from a capitation arrangement that would still be considered a full capitation arrangement. Specifically, we seek comment on whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services. We also seek comment on what percentage of the total cost of care such exclusions typically account for under what is intended to be a ''full'' global capitation arrangement. We also seek

comment on how non-Medicare payers define or prescribe certain categories of services that are excluded with regards to global capitation payment arrangements.

In addition, we are seeking comment on whether a capitation arrangement should be considered to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate under the full capitation standard for Other Payer Advanced APMs as discussed in section III.I.4.d.(2)(c)(ii) of this proposed rule.

(3) Summary of Proposals

In this section, we are proposing the following policy:

- *Expected Expenditures:* We are proposing to amend the definition of expected expenditures codified at § 414.1415(c)(5) to state, for the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures mean the episode target price. In addition, for purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the APM should not exceed the expected Medicare Parts A and B expenditures (including model-specific risk-adjustments and trend adjustments), for the APM Entity in the absence of the APM. If expected expenditures under the APM exceed the Medicare Parts A and B expenditures that the APM Entity would be expected to incur in the absence of the APM, such excess expenditures would not be considered when CMS assesses financial risk under the APM for Advanced APM determinations.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450). In the CY 2019 PFS final rule (83 FR 59923 through 59925), we finalized additional policies relating to QP determinations and Partial QP election to report to MIPS.

(2) Group Determination

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we finalized that QP determinations would generally be made at the APM Entity level, but for two exceptions in which we make the QP determination at the individual level: (1) Individuals participating in multiple Advanced APM Entities, none of which meet the QP threshold as a group; and (2) eligible clinicians on an Affiliated Practitioner List when that list is used for the QP determination because there are no eligible clinicians on a Participation List for the APM Entity (81 FR 77439 through 77443). As a result, the QP determination for the APM Entity would apply to all the individual eligible clinicians who are identified as part of the APM Entity participating in an Advanced APM. If that APM Entity's Threshold Score meets the relevant QP threshold, all individual eligible clinicians in that APM Entity would receive the same QP determination, applied to their NPIs, for the relevant year. The QP determination calculations are aggregated using data for all eligible clinicians participating in the APM Entity on a determination date during the QP Performance Period.

(b) Application of Partial QP Status

In the CY 2017 Quality Payment Program final rule (81 FR 77440), we stated that we would apply QP status at the NPI level instead of at the TIN/NPI level. We noted that an individual clinician identified by an NPI may have reassigned billing rights to multiple TINs, resulting in multiple TIN/NPI combinations being associated with one individual clinician (NPI). We also stated that if QP status was only applied to one of an individual clinician's multiple TIN/NPI combinations, an eligible clinician who is a QP for only one TIN/NPI combination might still have to report under MIPS for another TIN/NPI combination. Under that approach, the APM Incentive Payment would be based on only a fraction of the clinician's covered professional services instead of, as we believe is the most logical reading of the statute, all those services furnished by the individual clinician, as represented by an NPI. Therefore, we expressed our concern with applying QP status only to a specific TIN/NPI combination as it would not effectuate the goals of the APM incentive path of the Quality Payment Program to reward individual clinicians for their commitment to Advanced APM participation.

For Partial QPs, we currently apply Partial QP status at the NPI level across all TIN/NPI combinations, as we have for QP status. However, upon further consideration, and based on our experience implementing the Quality Payment Program to date, we no longer believe we should apply Partial QP status at the individual clinician (NPI) level across all TIN/NPI combinations, as we have and do for QP status. Partial QPs are excluded from MIPS based on an election made at the APM Entity or individual eligible clinician level, and this exclusion is currently applied at the NPI level across all of their TIN/NPI combinations. When this MIPS exclusion is applied at the NPI level, it does not always provide a similar net positive outcome across an individual clinician's TIN/NPI combinations when compared to the APM Incentive Payment that QPs receive. The MIPS exclusion is different from QP status as Partial QPs do not receive an APM Incentive Payment, Partial QPs are only relieved of the MIPS reporting requirements and not subject to a MIPS payment adjustment. As such, while a Partial QP might wish to be excluded from the MIPS reporting requirements and payment adjustment with respect to the TIN/NPI combination that relates to an APM Entity in an Advanced APM, that same Partial QP might benefit from reporting to MIPS and receiving a MIPS payment adjustment with respect to some or all of their other TIN/NPI combinations because they anticipate receiving an upward MIPS payment adjustment.

So, while the current policy excludes Partial QPs from MIPS reporting requirements and allows Partial QPs to avoid any potential downward MIPS payment adjustment, we have heard from stakeholders, including some clinicians, that this policy has prevented eligible clinicians from receiving a positive MIPS payment adjustment earned through a different TIN/NPI combination not associated with the APM Entity through which they attained Partial QP status. Furthermore, in many circumstances, the election to be excluded from MIPS for an eligible clinician is made outside their control at the APM Entity level. In such scenarios, an eligible clinician may have reported to MIPS as part of a group or as an individual under a separate TIN/NPI combination, but would not receive any MIPS payment adjustment based on that reporting. If eligible clinicians who would have received a positive MIPS adjustment are excluded from MIPS because of their Partial QP status, it could potentially discourage eligible clinicians from participating in Advanced APMs. Additionally, in future years of the Quality Payment Program, we anticipate that it will become harder to attain QP and Partial QP status because the QP and Partial QP payment amount and patient count thresholds will rise, as set forth in § 414.1430. As a result, a greater number of Advanced APM participants may attain Partial QP status, which we

believe increases the importance of removing the potential disincentive for Advanced APM participation based on the way the MIPS exclusion for Partial QPs is applied.

Therefore, we are proposing that beginning with the 2020 QP Performance Period, Partial QP status would apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status, and to amend our regulation by adding § 414.1425(d)(5) to reflect this change. This means that any MIPS election for a Partial QP would only apply to the TIN/NPI combination through which Partial QP status is attained, so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still be a MIPS eligible clinician and report under MIPS for other TIN/NPI combinations.

We seek comment on this proposal.

(3) QP Performance Period

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77446 through 77447), we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year. We finalized that during the QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

(b) APM Entity Termination

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1425(c)(5) and § 414.1425(d)(3) that an eligible clinician is not a QP or Partial QP for a year if the APM Entity group voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period (81 FR 77446 through 77447). We also finalized at § 414.1425(c)(6) and § 414.1425(d)(4) that an eligible clinician is not a QP or Partial QP for a year if one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP or Partial QP payment amount threshold or QP or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities (81 FR 77446 through 77447). We finalized these policies in part to ensure that APM Entities and eligible clinicians who achieve QP or Partial QP status during a QP Performance Period actually assume a more than a nominal amount of financial risk, as is necessary for Advanced APMs, for at least the full QP performance period from January 1 through August 31, if not the entire performance year under the Advanced APM.

Currently, under the terms of some Advanced APMs, APM Entities can terminate their participation in the Advanced APM while bearing no financial risk after the end of the QP Performance Period for the year (August 31). Under our current regulation, an APM Entity's termination after that date would not affect the QP or Partial QP status of all eligible clinicians in the APM Entity. We acknowledge that it may be appropriate for an Advanced APM to allow participating APM Entities to terminate without bearing financial risk for that performance period under the terms of the Advanced APM itself, including allowing such terminations to occur after the end of the QP Performance Period (August 31). However, allowing those eligible clinicians to retain their QP or Partial QP status without having borne financial risk under the Advanced APM through which they attained QP or Partial QP status is not aligned with the structure and principles of the Quality Payment Program, which is designed to reward those APM Entities and eligible clinicians for meaningfully assuming more than a nominal amount of financial risk, as required by the Advanced APM criteria. A critical aspect of Advanced APMs is that participants must bear more than a nominal amount of financial risk under the model. If an APM Entity terminates participation in the Advanced APM without financial accountability, the APM Entity has not yet borne more than a nominal amount of financial risk. As such, we do not believe it is appropriate for eligible clinicians in an APM Entity that terminates after QP determinations are made, but before bearing more than a nominal amount of financial risk, to retain any status as QPs or Partial QPs.

Therefore, regarding QP status, we are proposing to revise § 414.1425(c)(5) and add §§ 414.1425(c)(5)(i) and 414.1425(c)(5)(ii) which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; (2) or the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. In addition, we are proposing to revise § 414.1425(c)(6) and add §§ 414.1425(c)(6)(i) and § 414.1425(c)(6)(ii), which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

Regarding Partial QP status, we are also proposing to revise § 414.1425(d)(3) and add §§ 414.1425(d)(3)(i) and 414.1425(d)(3)(ii), which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or (2) the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. We are also proposing to revise § 414.1425(d)(4) and add §§ 414.1425(d)(4)(i) and 414.1425(d)(4)(ii), which states, beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates

voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities. We believe these additions account for the scenarios in which an APM Entity terminates from an Advanced APM at a date on which the APM Entity would not incur any financial accountability under the terms of the Advanced APM.

We seek comment on this proposal.

(4) Summary of Proposals

In this section, we are proposing the following policies:

- *Application of Partial QP Status:* We propose that beginning with the 2020 QP Performance Period, Partial QP status will apply only to the TIN/NPI combination(s) through which an individual eligible clinician attains Partial QP status. We propose to amend § 414.1425(d)(5) to reflect this change.
- *APM Entity Termination:* We propose to revise §§ 414.1425(c)(5), 414.1425(c)(6), 414.1425(d)(3), and 414.1425(d)(4) to state that an eligible clinician is not a QP or a Partial QP for the year when an APM Entity terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs.

e. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule (81 FR 77459), we finalized our overall approach to the All-Payer Combination Option. The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through payment arrangements offered by payers other than Medicare that CMS has determined meet the criteria to be Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements that satisfy the Other Payer Advanced APM criteria with payers other than Medicare. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461). We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score (that is, based on payment amount or patient count) that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

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TABLE 56: QP Payment Amount Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	25%	25%	25%
Total			50%	50%	75%
Partial QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			40%	40%	50%

TABLE 57: QP Patient Count Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			35%	35%	50%
Partial QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	10%	10%	10%
Total			25%	25%	35%

FIGURE 2: QP Determination Tree, Payment Years 2021-2022

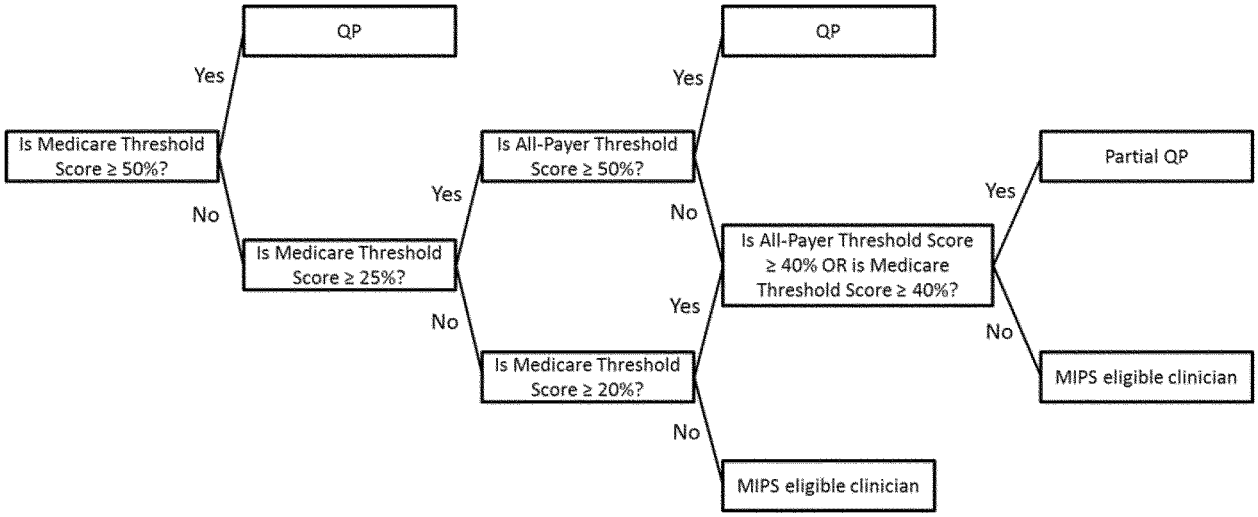
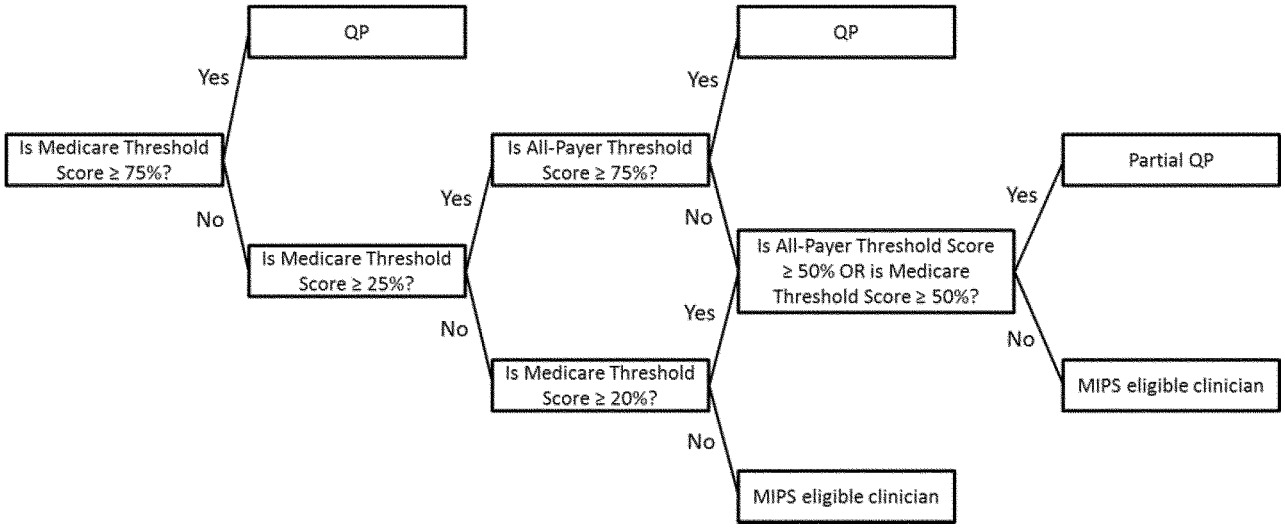


FIGURE 3: QP Determination Tree, Payment Years 2023 and Later



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Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether payment arrangements offered by other payers meet the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangements from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule (82 FR 53844 through 53890), we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies. A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891.

In the CY 2019 PFS final rule (83 FR 59926 through 59938), we finalized the following:

Other Payer Advanced APM Criteria:

- We changed the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each participating APM Entity group, or each hospital if hospitals are the APM Entities, use CEHRT to document and communicate clinical care.

• We allowed payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.

• We clarified § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

• We revised § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, that to be an Other Payer Advanced APM, an other payer arrangement must use an outcome measure, that must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

• We also revised our regulation at § 414.1420(c)(3)(i) to provide that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year that did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as finalized in CY 2019 PFS final rule (83 FR 55931 through 55932), we would continue to apply the previous requirements for purposes of those determinations. This revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

• We revised § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

Determination of Other Payer Advanced APMs:

• We finalized details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we aligned the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

• We eliminated the Payer Initiated Process that is specifically for CMS Multi-Payer Models. These payers will be able to submit their arrangements through the Payer Initiated Process for Remaining Other Payers as finalized in the CY 2019 PFS final rule (82 FR 59933 through 59935), or through the Medicaid or Medicare Health Plan payment arrangement submission processes, and no longer need a special pathway.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations:

• We added a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We modified our regulation at § 414.1440(d) by adding a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.

• We clarified that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We codified this clarification by amending § 414.1440(d)(1).

• We extended the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores.

In this section of the proposed rule, we address our proposal to define the term Aligned Other Payer Medical Home Model, and our proposals regarding bearing financial risk for monetary losses, specifically the Medicaid Medical Home Model financial risk standard and the definition of expected expenditures. We also discuss our request for comment on whether certain items and services should be excluded from the capitation rate for our definition of full capitation arrangements.

(2) Aligned Other Payer Medical Home Models

(a) Definition

As we explained when finalizing the definitions of Medical Home Model and Medicaid Medical Home Model in the CY 2017 Quality Payment Program final rule, MACRA does not define 'medical homes,' but sections 1848(q)(5)(C)(i), 1833(z)(2)(B)(iii)(II)(cc)(BB), 1833(z)(2)(C)(iii)(II)(cc)(BB), and 1833(z)(3)(D)(ii)(II) of the Act make medical homes an instrumental piece of the law (81 FR 77403). The terms Medical Home Model and Medicaid Medical Home Model are limited to Medicare and Medicaid payment arrangements, respectively, and do not include other payer payment arrangements.

As we discuss in section III.I.4.b. of this proposed rule, we are proposing to add the defined term ''Aligned Other Payer Medical Home Model'' to § 414.1305, which would mean an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by an other payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation with CMS, such as a memorandum of understanding (MOU), and is determined by CMS to have the following characteristics:

• The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

• Empanelment of each patient to a primary clinician; and

• At least four of the following: Planned coordination of chronic and preventive care; Patient access and continuity of care; risk-stratified care management; coordination of care across the medical neighborhood; patient and caregiver engagement; shared decision-making; and/or

payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

The proposed definition of Aligned Other Payer Medical Home Model includes the same characteristics as the definitions of Medical Home Model and Medicaid Medical Home Model, but it applies to other payer payment arrangements. We believe that structuring this proposed definition in this manner is appropriate because we recognize that there may be medical homes that are operated by other payers that may be appropriately considered medical home models under the All-Payer Combination Option.

We are proposing to exclude Medicaid payment arrangements from this proposed definition of Aligned Other Payer Medical Home Model because we have previously defined the term Medicaid Medical Home Model at § 414.1305 and we believe it is important to distinguish Medicaid payment arrangements from other payment arrangements, given the requirements in sections 1833(z)(2)(B)(ii)(I)(bb) and 1833(z)(3)(B)(ii)(I)(bb) of the Act requiring us to consider whether there is a medical home or alternative payment model under the Title XIX state plan in each state when making QP determinations using the All-Payer Combination Option.

For purposes of the Aligned Other Payer Medical Home Model definition, for an arrangement to be aligned, we mean through a written expression of alignment and cooperation with CMS, such as an MOU. CMS Multi-Payer Models require alignment across the different payers and a written expression reflects the fact that each arrangement has been reviewed by CMS and CMS has determined that the other payer payment arrangement is aligned with a CMS Multi-Payer Model that is a Medical Home Model. We are proposing to limit this Aligned Other Payer Medical Home Model definition to other payer payment arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models because we can be assured that the structure of these arrangements is similar to the Medical Home Models and Medicaid Medical Home Models for which we have already made a similar determination. Based on our experience to date, we anticipate that participants in these arrangements may generally be more limited in their ability to bear financial risk than other entities because they may be smaller and predominantly include primary care practitioners, whose revenues are a smaller fraction of the patients' total cost of care than those of other eligible clinicians. At the same time, we do not believe that participants in all medical homes, regardless of payer, face the same limitations on their ability to bear financial risk. We believe that some participants may have different organizational or financial circumstances that allow them to bear greater such risk. We believe that applying the proposed Aligned Other Payer Medical Home Model definition to all other payer payment arrangements would create potential new opportunities for gaming in commercial settings where we do not have control over the design of such models. However, we believe that payment arrangements that have been aligned and are similar to a Medicaid Home Model, where we have already put in place policies to control against gaming, would be similarly constrained.

In addition, we have acquired additional understanding of some other payer payment arrangements after one year of experience with the Payer Initiated Process, which included some arrangements that are aligned with CMS Multi-Payer Models that are Medical Home Models.

We seek comment on this proposal.

(b) Other Payer Advanced APM Criteria for Aligned Other Payer Medical Home Models

As defined in § 414.1305, an Other Payer Advanced APM is an other payer arrangement that meets the Other Payer Advanced APM criteria set forth in § 414.1420. Accordingly, we propose that the CEHRT criterion codified in § 414.1420(b) and the use of quality measures criterion codified in § 414.1420(c) would apply to any Aligned Other Payer Medical Home Model for which we would make an Other Payer Advanced APM determination. Further, we propose to revise § 414.1420(d)(8) to require Aligned Other Payer Medical Home Models to comply with the 50 eligible clinician limit to align with the requirements that apply to Medical Home Models and Medicaid Medical Home Models.

Regarding the applicable financial risk and nominal amount standards, consistent with the financial risk and nominal amount standards applicable to Medical Home Models and Medicaid Medical Home Models, we propose that the Aligned Other Payer Medical Home Model financial risk and nominal amount standards would be the same as the Medicaid Medical Home Model financial risk and nominal amount standards. We are proposing corresponding amendments to § 414.1420(d)(2) and (4) so that those sections note, Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard and Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard, respectively. We believe that this proposal, as described in section III.I.3.b. of this proposed rule, is appropriate because the same expectation of ability to bear a more than nominal amount of financial risk applies to participants in these models as Medical Home Models and Medicaid Medical Home Models because the arrangements are already aligned and the participants are the same.

(c) Determination of Aligned Other Payer Medical Home Model and Other Payer Advanced APM Status

We propose that payers may submit other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Payer Initiated Process. This proposal would be effective January 1, 2020 for the 2021 performance year. In the CY 2019 PFS final rule, we finalized a process for Remaining Other Payers to submit other payer arrangements for CMS determination of Other Payer Advanced APM status (83 FR 59934 through 59935). Other payers would be required to submit their other payer arrangements for CMS determination as Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, using this Remaining Other Payer process.

We propose that APM Entities and eligible clinicians can submit other payer arrangements for CMS to determine whether they are Aligned Other Payer Medical Home Models and Other Payer Advanced APMs, as applicable, through the Eligible Clinician Initiated Process.

We seek comment on these proposals.

(3) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77466), we divided the discussion of this criterion into two main topics: (1) What it means for an APM Entity to bear financial risk if actual aggregate expenditures exceed expected aggregate expenditures under a payment arrangement (which we refer to as either the generally applicable financial risk standard or Medicaid Medical Home Model financial risk standard); and (2) what levels of risk we would consider to be in excess of a

nominal amount (which we refer to as either the generally applicable nominal amount standard or the Medicaid Medical Home Model nominal amount standard).

In the CY 2017 Quality Payment Program final rule, we finalized that for a Medicaid Medical Home Model to be an Other Payer Advanced APM, if the APM Entity's actual aggregate expenditures exceed expected aggregate expenditures, the Medicaid Medical Home Model must:

- Withhold payment for services in the APM Entity and/or the APM Entity's eligible clinicians;
- Reduce payment rates to the APM Entity and/or the APM Entity's eligible clinicians;
- Require direct payment by the APM Entity to the Medicaid program; or
- Require the APM Entity to lose the right to all or part of an otherwise guaranteed payment or payments.

We based this standard on our belief that Medicaid Medical Home Models are unique types of Medicaid APMs because they are identified and treated differently under the statute. We believe it is appropriate to establish a unique standard for bearing financial risk that reflects these statutory differences and remains consistent with the statutory scheme, which is to provide incentives for participation by eligible clinicians in Advanced APMs (81 FR 77467 through 77468).

In addition, to be an Other Payer Advanced APM, a Medicaid Medical Home Model must require that the total annual amount that an APM Entity potentially owes or foregoes under the Medicaid Medical Home Model must be at least:

- For QP Performance Period 2019, 3 percent of the APM Entity's total revenue under the payer.
- For QP Performance Period 2020, 4 percent of the APM Entity's total revenue under the payer.
- For QP Performance Period 2021 and later, 5 percent of the APM Entity's total revenue under the payer.

(b) Aligned Other Payer Medical Home Model Financial Risk and Nominal Amount Standards

Neither the current Medical Home Model financial risk and nominal amount standards nor the Medicaid Medical Home Model financial risk and nominal amount standards do not apply to similar arrangements with other payers for purposes of Other Payer Advanced APM determinations. Consistent with our proposal to define the term Aligned Other Payer Medical Home Model, we are proposing to amend § 414.1420(d)(2) and (d)(4) of our regulations to also include that conform the financial risk and nominal amount standards for Aligned Other Payer Medical Home Models with the existing Medicaid Medical Home Model financial risk and nominal amount standards for Medicaid Medical Home Models. Consistent with recognizing the similar characteristics of these payment arrangements and the same participants, we believe that the same financial risk and nominal amount standards should be applied to Aligned Other Payer Medical Home Models.

Further, we are proposing a corresponding amendment to § 414.1420(d)(2)(ii) to state that an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model require the direct payment by the APM Entity to the payer, which meaning either the other payer or the Medicaid agency.

We believe that if we applied the Medicaid Medical Home Model financial risk and nominal amount standards to all other payer arrangements that would meet the Aligned Other Payer Medical Home Model definition but for not being aligned with a CMS Multi-Payer Model that is a Medical Home Model, we might create gaming opportunities amongst other payers where medical homes are developed solely to take advantage of the unique nominal amount standard, particularly because we would have less insight into the nature of arrangements not aligned with CMS Multi-Payer Models.

In addition, as the 50 eligible clinician limit as codified in §§ 414.1415(c)(7) and 414.1420(d)(8) currently applies to Medical Home Models and Medicaid Medical Home Models, respectively, we correspondingly propose that the 50 eligible clinician limit apply to Aligned Other Payer Medical Home Models by amending § 414.1420(d)(8).

We seek comment on these proposals.

(b) Generally Applicable Other Payer Advanced APM Nominal Amount Standard

(i) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77471), we finalized at § 414.1420(d)(3)(ii) that except for risk arrangements described under the Medicaid Medical Home Model Standard, for a payment arrangement to meet the nominal amount standard the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and total potential risk must be at least 4 percent of the expected expenditures. Furthermore, we finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement. Section 414.1420(d)(6) provides for the purposes of this section, expected expenditures is defined as the Other Payer Advanced APM benchmark, except for episode payment models, for which it is defined as the episode target price.

(ii) Marginal Risk

As we stated in the 2017 Quality Payment Program final rule (81 FR 77470), to determine that a payment arrangement satisfies the marginal risk portion of the nominal amount standard, we would examine the payment required under the payment arrangement as a percentage of the amount by which actual expenditures exceeded expected expenditures. Specifically for marginal risk, we finalized that for a payment arrangement to meet the nominal amount standard, the specific level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures. We also stated that the rate of marginal risk could vary with the amount of losses.

To date, we have applied the marginal risk requirement as requiring that a payment arrangement must exceed the marginal risk rate of 30 percent at all levels of total losses even as the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, consistent with § 414.1420(d)(5)(i). For example, certain other payer arrangements where the marginal risk met or exceeded 30 percent at lower levels of losses in excess of expected expenditures, but fell below 30 percent at higher levels of losses, would not meet the marginal risk requirement of the generally applicable nominal amount standard.

In general, this approach has worked well and served its intended purpose of ensuring only other payer arrangements with strong financial risk components are determined to be Other Payer Advanced APMs. At the same time, this policy has necessitated that we determine that certain other payer arrangements are not Other Payer Advanced APMs even though they include strong financial risk components and well exceed the 30 percent marginal risk requirement at the most common levels of losses in excess of expected expenditures, and employ marginal risk rates below 30 percent only at much higher levels of losses. We

do not believe these other payer arrangements include marginal risk rates below 30 percent to avoid subjecting participants to more than nominal amounts of risk. Rather, we believe that these other payer arrangements employ the lower marginal risk rates at higher levels of losses in order to protect participants from potentially catastrophic losses and undue financial burden that might arise because of market factors likely outside their control.

Therefore, we propose to amend § 414.1420(d)(5) by amending paragraph (d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses and small losses as described in paragraphs (d)(5)(ii) and (d)(5)(iii) of this section.

We would calculate the average marginal risk rate in two steps. An example of such a calculation is presented in Table 58. This example uses a model relying on a Total Cost of Care (TCOC) benchmark. This methodology can also be applied to other types of other payer payment arrangements. In this example, first, take the sum of the marginal risk for each percent above the Total Cost of Care (TCOC) benchmark to determine the participant losses. For example, at 3 percent add 50 percent (amount for 1 percent above benchmark) plus 50 percent (amount for 2 percent above benchmark) plus 50 percent (amount for 3 percent above benchmark) equals 1.50 percent. Second, divide the participant losses by the percentage above the benchmark (in our example, 1.50 percent divided by 3) to get average marginal risk. The average marginal risk rate remains above 30 percent at all levels of potential losses up to point where the participant would be responsible for losses equal to the total potential risk requirement of 3 percent. We note that this example presents the calculation only up to the point where the total potential risk requirement is met.

TABLE 58—EXAMPLE AVERAGE MARGINAL RISK CALCULATION

Performance (% above TCOC benchmark)	Marginal risk (%)	Participant losses (%)	Average marginal risk (%)
1	50	0.50	50
2	50	1.00	50
3	50	1.50	50
4	25	1.75	44
5	25	2.00	40
6	25	2.25	38
7	25	2.50	36
8	25	2.75	34
9	25	3.00	33

Through this amendment, significant and meaningful financial risk would continue to be required for Other Payer Advanced APMs because the average marginal risk rate would need to be or exceed 30 percent, while recognizing that such risk can be demonstrated with some variation in the application of marginal risk rates, allowing for continued innovation in the marketplace. This proposed policy ensures that all Other Payer Advanced APMs have 30 percent of marginal risk up until the participant owes 3 percent of losses, which is the intended effect of the standard without excluding certain payment arrangement that have strong financial risk designs. When considering average marginal risk in the context of total risk, as we do for Other Payer Advanced APM determinations, certain risk arrangements can create meaningful and significant risk-based incentives for performance and at the same time ensure that the payment arrangement has strong financial risk components.

We believe this proposed change is consistent with the statute and the use of guardrails to maintain financially strong models, and note that in making this change we are not lowering the standard for the applicable marginal risk rate but rather allowing for a new demonstration of how it can be met. We clarify that the proposed amendment would also continue to maintain the allowance for large losses provision as described in paragraph (d)(5)(ii) of § 414.1420, so that when calculating the average marginal risk rate we may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the payment arrangement greater than or equal to the total risk requirements. We also clarify that the exception for small losses described in paragraph (d)(5)(iii) would also be maintained.

We seek comment on this proposal.

(iii) Expected Expenditures

In the CY 2017 Quality Payment Program final rule (81 FR 77551), we established the definition of ''expected expenditures'' at § 414.1420(d)(6) to mean the Other Payer APM benchmark, except for episode payment models, for which it is defined as the episode target price. We also finalized at § 414.1420(d)(3)(ii) that, except for arrangements assessed under the Medicaid Medical Home Model financial risk and nominal amount standards, in order to meet the Other Payer Advanced APM nominal amount standard, a payment arrangement's level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures and the total potential risk must be at least 4 percent (81 FR 77471).

In the CY 2017 Quality Payment Program proposed rule (81 FR 28332), we proposed to measure three dimensions of risk under our generally applicable nominal amount standards: (1) Marginal risk, which refers to the percentage of the amount by which actual expenditures exceed expected expenditures for which an APM Entity would be liable under the APM; (2) minimum loss rate (MLR), which is a percentage by which actual expenditures may exceed expected expenditures without triggering financial risk; and (3) total potential risk, which refers to the maximum potential payment for which an APM Entity could be liable under the APM. However, based on commenters' concerns regarding technical complexity, we finalized only the marginal risk and MLR requirements.

In the CY 2017 Quality Payment Program proposed rule (81 FR 28333), we explained that to determine whether an APM satisfies the marginal risk portion of the nominal risk standard, we would examine the payment required under the APM as a percentage of the amount by which actual expenditures exceeded expected expenditures. We proposed that we would require that this percentage exceed a required marginal risk percentage of 30 percent regardless of the amount by which actual expenditures exceeded expected expenditures.

Our rationale for proposing the marginal risk requirement was that the inclusion of a marginal risk requirement would be intended to focus on maintaining a more than nominal level of likely risk under an Advanced APM or an Other Payer Advanced APM. However, even with a marginal risk requirement, as there is under the Other Payer Advanced APM criteria, we believe there is a need to amend the definition of expected expenditures to ensure there are more than nominal levels of average or likely risk under Other Payer Advanced APMs that meets the generally applicable benchmark-based nominal amount standard. Even with the current marginal risk requirement, a more rigorous definition of expected expenditures is needed to avoid situations where the level of expected expenditures would be set in a manner that reduces the losses a participant might incur. We also believe it is important that our definition of expected expenditures is consistent across both the Advanced APM and Other Payer Advanced APM criteria. We generally try to align the Advanced APM and Other Payer Advanced APM criteria to the extent feasible and appropriate.

As discussed in section III.I.4.c.(2)(c) of this proposed rule, this proposal is intended to account for scenarios where a payment arrangement could have a sufficient total risk potential to meet our standard and a sharing rate that results in adequate marginal risk if actual expenditures exceed expected expenditures; however, the level of expected expenditures reflected in the payment arrangements benchmark or episode target price could be set in a manner which substantially reduces the amount of loss a participant in the payment arrangement would reasonably expect to incur.

For a payment arrangement to meet the generally applicable benchmark-based nominal amount standard, we believe there should be not only the potential for financial losses based on expenditures in excess of the benchmark as provided in § 414.1420(d)(6), but also some meaningful likelihood that a participant might exceed the benchmark. If the benchmark is set in such a way that it is extremely unlikely that participants would exceed it, then there is little potential for participants to incur financial losses, and the amount of risk is essentially illusory.

Therefore, in § 414.1420(d)(6), we are proposing to amend the definition of expected expenditures. Specifically, we would define expected expenditures as, for the purposes of this section, as the Other Payer APM benchmark. For episode payment models, expected expenditures mean the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures (that is, benchmarks) under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement such excess expenditures are not considered when CMS assesses financial risk under the payment arrangement for Other Payer Advanced APM determinations.

We believe that this proposed change would prevent the expected expenditures under the other payer payment arrangement being set in a manner which substantially reduces the amount of losses a participant may face while otherwise satisfying this Other Payer Advanced APM criterion.

We clarify that, in general, expected expenditures are expressed as a dollar amount, and may be derived from national, regional, APM Entity-specific, and/or practice-specific historical expenditures during a baseline period, or other comparable expenditures. However, we recognize expected expenditures under a payment arrangement are often risk-adjusted and trended forward, and may be adjusted to account for expenditure changes that are expected to occur as a result of payment arrangement participation. For the purpose of this proposed definition of expected expenditures, we would not consider risk adjustments to be excess expenditures when comparing to the costs that an APM Entity would be expected to incur in the absence of the payment arrangement.

We believe that this proposed amendment would allow us to ensure that there are more-than-nominal amounts of average or likely risk under an other payer payment arrangement that meets the generally applicable benchmark-based nominal amount standard. We believe that the proposed amended definition of expected expenditures, particularly by our not considering excess expenditures, would provide a more definite basis for us to assess whether an APM Entity would bear more than a nominal amount of financial risk for participants under the generally applicable benchmark-based nominal amount standard.

We seek comment on this proposal.

(iv) Excluded Items and Services Under Full Capitation Arrangements

In the CY 2017 Quality Payment Program final rule (81 FR 77551), we finalized a capitation standard at § 414.1420(d)(7) which provides a capitation arrangement meets the Other Payer Advanced APM financial risk criterion. For purposes of § 414.1420(d)(3), we defined a capitation arrangement as a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the APM Entity. We clarified that arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program are not considered capitation arrangements for purposes of § 414.1420(d)(7).

In the CY 2019 PFS final rule (83 FR 59939), we made technical corrections to the Advanced APM financial risk capitation standard at § 414.1420(d)(7). These corrections clarified that our financial risk capitation standard applies only to full capitation arrangements where a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement or reconciliation is performed.

As we have begun to collect information on other payer payment arrangements for purposes of making Other Payer Advanced APM determinations, we have noticed that some payment arrangements that are submitted for CMS to determine as capitation arrangements consistent with § 414.1420(d)(7) include a list of services that have been excluded from the capitation rate, such as hospice care, organ transplants, or out-of-network emergency room services. In reviewing

these exclusion lists, we believe that it may be appropriate for CMS to allow certain capitation arrangement to be considered ''full'' capitation arrangements even if they categorically exclude certain services from payment through the capitation rate. Therefore, we are seeking comment on how other payers define or determine what, if any, exclusions are reasonable in a given capitation arrangement. Specifically, we seek comment on whether there are common industry practices to exclude certain categories of items and services from capitated payment rates and, if so, whether there are common principles or reasons for excluding those categories of services. In addition, we seek comment on why such items or services are excluded.

We also seek comment on how non-Medicare payers define or prescribe certain categories of services that are excluded with regards to global capitation payment arrangements. We also seek comment on whether a capitation arrangement should be considered to be a full capitation arrangement even though it excludes certain categories of services from the capitation rate under a full capitation arrangement.

(4) Summary of Proposals

In this section, we are proposing the following policies:

- *Aligned Other Payer Medical Home Model:* We proposed to define the term Aligned Other Payer Medical Home Model. We also propose to apply the existing Medicaid Medical Home Model financial risk and nominal amount standards, including the 50 eligible clinician limit, to Aligned Other Payer Medical Home Models.
- *Marginal Risk:* We propose that when that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate requirement, with exceptions for large losses and small losses as provided in § 414.1420(d)(5).
- *Expected Expenditures:* We are proposing to amend the definition of expected expenditures codified at § 414.1420(d)(6) to define expected expenditures as the Other Payer Advanced APM benchmark, and, for episode payment models, expected expenditures means the episode target price.

5. Quality Payment Program Technical Revisions

We are proposing certain technical revisions to our regulations to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

We are proposing a technical revision to § 414.1405(f) of our regulations to specify that the exception for the application of the MIPS payment adjustment factors to model-specific payments is applicable starting in the 2019 MIPS payment year, not just for the 2019 MIPS payment year. This proposed revision would align the regulation text with our final policy as stated in the preamble of the CY 2019 PFS final rule with comment period (83 FR 59887 through 59888) which makes clear that the exception begins with the 2019 MIPS payment year and continues in subsequent years.

We are also proposing technical revisions to Table 59 of the CY 2019 PFS final rule with comment period (83 FR 59935) to correct two dates. Specifically we propose to change the date for Medicare Health Plans: Guidance made available to ECs, then Submission Period Opens; it is currently listed as September 2020, and we propose to change that date to August 2020. Similarly, we propose to change the date for Remaining Other Payers: Guidance made available to ECs, then Submission Period Opens; it is currently listed as September 2020, and we propose to change that to August 2020. These changes align with what was originally finalized in the CY 2018 QPP final rule with comment period (82 FR 53864) which stated that the dates were to be August 2020, and which we did not intend to change in the CY 2019 PFS final rule. Table 59 is included as the corrected Table 59 from the CY 2019 PFS final rule.

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TABLE 59: Proposed Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020

	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date
Medicaid	Guidance sent to states, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2019
	Submission Period Closes	April 2019	Submission Period Closes	November 2019
	CMS contacts states and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List	December 2019
Medicare Health Plans	Guidance made available to Medicare Health Plans, then Submission Period Opens	April 2019	Guidance made available to ECs, then Submission Period Opens	August 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List	December 2020
Remaining Other Payers	Guidance made available to Remaining Other Payers, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	August 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List	December 2020

*Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

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We are also proposing technical revisions to §§ 414.1415(c)(6) and 414.1420(d)(7) to correct the internal citation. The current citation, 42 U.S.C. 422, is incorrect. It should instead be 42 CFR part 422. We also are proposing technical revisions to § 414.1420(d)(5). We clarify that ''APM'' in § 414.1420(d)(5) should be ''other payer payment arrangement.'' In the CY 2019 PFS final rule, we finalized deleting § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii), but that change was not applied to the regulation. We are proposing to revise the regulation accordingly in this proposed rule. Relatedly, we propose to amend § 414.1420(d)(i), (ii), and (iii) to state in ''paragraph (d)(3)(ii)'' of this section instead of ''paragraph (d)(3)(ii)(A)'' of this section. We are also proposing to clarify that ''Other Payer Advanced APM'' in § 414.1420(d)(5)(ii) should be ''other payer payment arrangement,'' as the marginal risk rate requirements are applied to any other payer payment arrangement that CMS assesses against the Other Payer Advanced APM criteria. These proposed revisions are technical in nature and do not change any substantive policies for the Quality Payment Program.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements (ICRs).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/*

oes/current/oes_nat.htm). In this regard, Table 60 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 60—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43–3021	19.00	19.00	38.00
Bookkeeping, Accounting, and Auditing Clerks	43–3031	22.46	22.46	44.92
Chief Executive	11–1011	96.22	96.22	192.44
Compliance Officer	13–1041	41.85	41.85	83.70
Computer Systems Analysts	15–1121	45.01	45.01	90.02
Health Diagnosing and Treating Practitioners	29–1000	49.02	49.02	98.04
Licensed Practical Nurse (LPN)	29–2061	22.62	22.62	45.24
Medical Secretary	43–6013	17.83	17.83	35.66
Physicians	29–1060	101.43	101.43	202.86
Practice Administrator (Medical and Health Services Managers)	11–9111	54.68	54.68	109.36

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs) (§§ 414.800 Through 414.806)

As described in section II.G. of this rule, section 2005 of the SUPPORT for Patients and Communities Act establishes a new Medicare Part B benefit for OUD treatment services furnished by OTPs for episodes of care beginning on or after January 1, 2020. In this rule, CMS proposes to use the payment methodology in section 1847A of the Act, which is based on Average Sales Price (ASP), to set the payment rates for the ''incident to'' drugs and ASP-based payment to set the payment rates for the oral product categories when we receive manufacturers' voluntarily-submitted ASP data for these drugs.

The proposed burden consists of the time/cost for manufacturers of oral opioid agonist or antagonist treatment medications (that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in the treatment of OUD) to voluntarily prepare and submit their ASP data to CMS.

The burden for such reporting is currently approved by OMB under control number 0938–0921 (CMS–10110) and would remain unchanged (13 hours per response, 4 responses per year, 180 respondents, and 9,360 total hours) since our currently approved burden already accounts for the voluntary reporting of ASP data. We estimate that there are approximately 15 manufacturers of oral drugs used for treatment of opioid use disorder (OUD). We believe that approximately 10 of the 15 manufacturers already report ASP data to CMS for other drugs, and thus up to 5 manufacturers may newly report ASP data to CMS. However, we note that some of these new respondents may have subsidiary or similar relationships with manufacturers that already report ASP data and may be able to submit their data with a current respondent. While this rule's proposed requirements may slightly increase the number of respondents, our 180 respondent per quarter estimate historically fluctuates over time as new Part B drug manufacturers are added while others leave or consolidate. The annual fluctuation in respondents in the past has typically been +/− 5 to 10 manufacturers per year; over the past few years, the annual fluctuation has sometimes been greater, ranging from −13 to +11, but over that several year period the overall average of the annual fluctuation is near 0. As a result, the potential slight increase in respondents associated with voluntary reporting from oral OUD drug manufacturers is well within the range of recent fluctuations in the number or respondents, and the net figure, taking into account voluntary OTP reporting, remains unchanged from the currently approved burden estimate at 180 respondents. In addition, we believe that additional voluntary reporting for oral drugs used for treatment of OUD for those manufacturers that currently report ASP data to CMS would impose minimal additional burden. Consequently, we are not making any changes under the aforementioned control number. However, we will continue to monitor the number of respondents to account for various factors such as a change in the number of voluntary submissions from oral OUD drug manufacturers, as well as other issues that may not be related to the voluntary reporting for oral drugs used in OTPs, such as manufacturer consolidations, and new Part B drug and biological manufacturers. We will revise the burden estimate as needed.

2. ICRs Regarding the Ground Ambulance Data Collection System

Section 1834(l)(17)(A) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, we are not setting out the burden of the proposed collection of information under the data collection system. Please refer to section VI.F.2. of this proposed rule for a discussion of the estimated impacts associated with the ground ambulance data collection system.

3. ICRs Regarding Intensive Cardiac Rehabilitation (§ 410.49)

Section 410.49(b)(1)(vii) and (viii) of this proposed rule would expand the covered conditions to chronic heart failure and add other cardiac conditions as specified through the national coverage determination (NCD) process. The proposed rule would expand covered conditions, but, due to the breadth of the proposed and existing covered conditions, we do not anticipate the need to use the NCD process to add additional covered conditions in the near future. In the unlikely event an NCD request was submitted, it would be covered by OMB control number 0938–0776 (CMS–R–290), which will not expire until February 29, 2020. We are not proposing any changes under that control number since we are not proposing any changes to the submission process or burden.

4. ICRs Regarding the Medicare Shared Savings Program (42 CFR part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to section VI.E.6. of this proposed rule for a discussion of the impacts associated with the proposed changes to the Shared Savings Program quality reporting requirements included in this proposed rule.

5. ICRs Regarding the Open Payments Program

As described in section III.F. of this rule, we propose to: (1) Expand the definition of ''covered recipient,'' (2) modify ''nature of payment'' categories, and (3) standardize data on reported covered drugs, devices, biologicals, or medical supplies.

Expanding the Definition of ''Covered Recipient'' (§§ 403.902, 403.904, and 403.908): In this rule we propose to expand the definition of a ''covered recipient'' in accordance with the SUPPORT Act to include physician assistants, nurse practitioners, clinical nurse specialists, nurse anesthetists, and certified nurse midwifes. The definition currently includes certain physicians and teaching hospitals. Section 6111(c) of the SUPPORT Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient included in the SUPPORT Act. In this regard we are not setting out burden under the authority of the PRA. . We do, however, provide a brief estimate in section V.8 of this proposed rule.

Modification of the ''Nature of Payment'' Categories (§§ 403.902 and 403.904): The following proposed changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). Subject to renewal, the control number is currently set to expire on March 31, 2021. It was last approved on March 21, 2018, and remains active.

The proposed changes would modify the ''nature of payment'' categories and provide more options for applicable manufacturers and GPOs to capture the nature of the payment made to the covered recipient. To accommodate this change, we project that reporting entities would need to update their system to incorporate the proposed categories. We estimate, based on the trends in the number of entities that report every year, that there are 1,600 reporting entities and estimate, using the number of records that these entities report as a proxy for size of the entity. While the total number of entities that report fluctuates year to year, but has been close to 1,600 for the last two program years. We also estimate that 38 percent (or 611 entities) are small, 29 percent (or 457 entities) are medium, and 33 percent (or 532 entities) are large. We also estimate that 25 percent of reporting entities (400) would need to make minor, one-time updates to their data collection processes because they expect to report a transaction with one of the new categories. Among the 400 entities, we estimate it would take between 5 and 30 hours per entity depending on the size of the entity (with large companies requiring more time) at $44.92/hr for support staff. For all of these entities, we estimate a subtotal of 5,895 hours [(30 hrs for a large entity × 133 entities) + (10 hrs for a medium entity × 114 entities) + (5 hrs for a small entity × 153 entities)] at a cost of $264,804 (5,895 hrs × $44.92/hr).

We also expect that all entities would need to make minor, one-time adjustments to their submission processes. For each entity we estimate that this would take 2 to 5 hours at $44.92/hr (with larger entities requiring more time) for support staff and 1 hour at $83.70/hr for compliance officers. For all entities, we estimate a subtotal of 7,767 hours [(5 hrs for support staff at a large entity × 532 entities) + (5 hrs for support staff at a medium entity × 457 entities) + (2 hrs for support staff at a small entity × 611 entities) + (1 hr for compliance officer at each entity regardless of size × 1600 entities)] at a cost of $410,941 [(2,660 hrs for support staff at large entities × $44.92/hr) + (2,285 hrs for support staff at medium entities × $44.92/hr) + (1,222 hrs for support staff at small entities × $44.92/hr) + (1,600 hrs for compliance officers across all entities × $83.70/hr)].

In aggregate, we estimate a one-time burden of 13,662 hours (5,895 hrs + 7,767 hrs) at a cost of $675,745 ($264,804 + $410,941) to implement. After these adjustments are made, we do not anticipate any ongoing added burden beyond what is currently approved under the aforementioned control number.

TABLE 61—BURDEN TO MODIFY NATURE OF PAYMENT CATEGORIES

Description	Hours	Cost
Burden to update collection processes for entities that expect to report a transaction with a new Nature of Payment category	5,895	$264,804
Burden to update submission processes and systems to account for the new Nature of Payment categories	7,767	410,941
Total	13,662	675,745

Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies (§§ 403.902 and 403.904): The following proposed changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). Subject to renewal, the control number is currently set to expire on March 31, 2021. It was last approved on March 21, 2018, and remains active.

Applicable manufacturers and GPOs will need to accommodate the reporting of device identifiers. We have made some estimates below, but we recognize that these estimates may vary because the information collection system

changes that are needed will vary since some entities may already be capturing this information in their systems while others may not. Nevertheless, we have made some assumptions below, but we welcome feedback from stakeholders regarding the potential burden associated with this proposal and the extent to which device identifiers are already tracked by reporting entities.

We estimate, based on an analysis of currently available data, that approximately 850 entities (approximately 53 percent of an assumed 1,600) would need to report at least one record with a device identifier and that 450 of those entities do not already collect the device identifier. For this analysis we assumed that 38 percent of the entities would be small, 29 percent would be medium, and 33 percent would be large. We differentiate because we assume that larger companies would incur more burden to make the changes needed to begin reporting device identifiers because they have more complex systems and potentially more records to report. The number of records submissions would not change, but this rule would add a new data element that may need to be reported along with some or all of an entity's records. The precise tasks would vary by entity, but may include developing processes for gathering device identifier information or systems for collecting the data.

For the 450 entities that would be required to start collecting device identifiers, we estimate that this task would take between 20 and 100 hours for support staff depending on the size of the company (with larger companies requiring more time) at $44.92/hr. For all entities, we estimate a subtotal of 24,840 hours [(100 hrs for a large entity × 150 entities) + (50 hrs for a medium entity × 128 entities) + (20 hrs for a small entity × 172 entities)] at a cost of $1,115,813 [(15,000 hrs for support staff at a large entity × $44.92/hr) + (6,400 hrs for support staff at a medium entity × $44.92/hr) + (3,440 hrs for support staff at a small entity × $44.92/hr)].

For the 850 entities that we expect would be required to begin reporting a device identifier, we estimate that this would take support staff between 10 and 40 hours per entity (with larger companies requiring more time) at $44.92/hr and 2 hours at $83.70/hr for compliance officers. For all entities, we estimate a subtotal of 21,100 hours [(40 hrs for support staff at a large entity × 282 entities) + (20 hrs for support staff at a medium entity × 244 entities) + (10 hrs for support staff at a small entity × 324 entities) + (2 hrs for compliance officers at every entity regardless of size × 850 entities)] at a cost of $1,013,740 [(11,280 hrs for support staff at large entities × $44.92/hr) + (4,880 for support staff at medium entities × $44.92/hr) + (3,240 for support staff at small entities × $44.92/hr) + (1,700 hrs for compliance officers across all entities regardless of size × $83.70/hr)].

We also assume that the remaining 750 entities not planning to submit a device identifier would have a small amount of burden associated with updating their submission processes. We estimate that this would take support staff between 2 and 10 hours per entity (with larger entities requiring more time) at $44.92/hr and 2 hours for compliance officers at $83.70/hr. For all entities, we estimate a subtotal of 5,637 hours [(10 hrs for support staff at a large entity × 249 entities) + (5 hrs for support staff at a medium entity × 215 entities) + (2 hrs for support staff at a small entity × 286 entities) + (750 hrs for compliance officers at all entities regardless of size × 2 hrs)] at a cost of $311,384 [(2,490 hrs for support staff at large entities × $44.92/hr) + (1,075 hrs for support staff at medium entities × $44.92/hr) + (572 hrs for support staff at small entities × $44.92/hr) + (1,500 hrs for compliance officers at all entities regardless of size × $83.70/hr)].

In aggregate, we estimate a one-time burden of 51,577 hours (24,840 hrs + 21,100 hrs + 5,637 hrs) at a cost of $2,440,937 ($1,115,813 + $1,013,740 + $311,384) to implement. After these adjustments are made, we do not anticipate there being any ongoing added burden beyond what is currently approved under the aforementioned control number.

TABLE 62—BURDEN FOR CHANGES TO STANDARDIZE DATA ON REPORTED COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES

Description	Hours	Cost
First year data collection burden for entities that do not currently collect a device identifier	24,840	$1,115,813
First year submission burden for all entities that would be required to report a device identifier	21,100	1,013,740
One time submission process and system updates for entities not reporting a device identifier	5,637	311,384
Total	51,577	2,440,937

6. ICRs Regarding Medicare Enrollment of Opioid Treatment Programs

Except as noted otherwise, the following proposed changes will be submitted to OMB for approval under control number 0938–0685 (CMS–855B; ''Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers'').

As discussed previously in this rule, we propose that OTP providers be required to enroll in Medicare via the paper or internet-based version of the Form CMS–855B (or its successor application) and any applicable supplement, pay the application fee, submit fingerprints, and complete a provider agreement.

Based on SAMHSA statistics and our internal data, we generally estimate that: (1) There are about 1,700 certified and accredited OTPs eligible for Medicare enrollment; and (2) 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year), bringing the total amount of OTPs eligible to enroll to approximately 1,900 over the next 3 years.

Form Completion: We estimate that it would take each OTP an average of 3 hours to obtain and furnish the information on the Form CMS–855B and a new supplement thereto designed to capture information unique to OTPs. Per our experience, we believe that the OTP's medical secretary would be responsible for securing and reporting data on the Form CMS–855B and new accompanying OTP supplement. We estimate that this task would take approximately 2.5 hours; of this amount, roughly 30 minutes would involve completion of the data on the supplement, though this timeframe could be higher or lower depending upon the number of individuals whom the OTP must list. Additionally, the form would be reviewed and signed by a health diagnosing and treating practitioner of the OTP, a process we estimate would take 0.5 hours. We thus project a first-year burden of 5,301 hours (1,767 entities × 3 hr) at a cost of $732,439 (5,301 hr × ((2.5 hr × $35.66/

hr) + (0.5 hr × $98.04/hr)), a second-year burden of 201 hours (67 entities × 3 hr) at a cost of $27,772 (201 hr × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)), and a third-year burden of 198 hours (66 entities × 3 hr) at a cost of $27,358 (198 hr x((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)). In aggregate, we estimate a burden of 5,700 hours (5,301 hr + 201 hr + 198 hr) at a cost of $787,569 ($732,439 + $27,772 + $27,358). When annualized over the 3-year period, we estimate an annual burden of 1,900 hours (5,700 hours/3) at a cost of $262,523 ($787,569/3).

A copy of the draft OTP supplement will be available on-line, and we welcome public comment on: (1) Its contents; (2) the usefulness of the data to be captured thereon; and (3) the anticipated burden of completion.

Fingerprinting: As we are proposing that OTPs be subject to high categorical risk level screening under § 424.518, we would require the submission of a set of fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP. The burden is currently approved by OMB under control number 1110–0046. An analysis of the impact of this proposed requirement can be found in the RIA section of this rule.

Application Fee: As already discussed in this rule, each OTP would be required to pay an application fee at the time of enrollment. The application fee does not meet the definition of a ''collection of information'' and, as such, is not subject to the requirements of the PRA. Although we are not setting out such burden under this section of the preamble, the cost is scored under the RIA section.

Provider Agreement: As mentioned in the preamble of this proposed rule, OTPs would have to complete a provider agreement in order to enroll in Medicare. The burden for reporting and completing the Provider Agreement—CMS Form 1561 and 1561A (OMB control number 0938–0832) are based on SAMHSA statistics. We generally estimate that there are about 1,700 already certified and accredited OTPs eligible for Medicare enrollment initially; and approximately 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year). We anticipate would take the OPT 5 minutes at $192.44/hr for a Chief Executive to review and sign the CMS 1561 or CMS 1561A, and an additional 5 minutes at $35.66/hr for a Medical Secretary to file the document when fully executed.

In aggregate, we estimate a burden of 317 hours ([1,767 OPTs for year 1 + 67 OTPs for year 2 + 67 OTPs for year 3] × 10 min/60) at a cost of $36,154 ([317 hr/2 respondents × $192.44/hr] + [317 hr/2 respondents × $35.66/hr]). This results, roughly, in a Year 1 burden of 295 hours at $33,623, a Year 2 burden of 11 hours at $1,272, and a Year 3 burden of 11 hours at a cost of $1,254. Annually, over the course of OMB's typical 3-year approval period, we estimate a burden of 106 hours 317 hr/3 years) at a cost of $12,051 ($36,154/3 years).

Total: Table 63 summarizes our foregoing burden estimates.

TABLE 63—COMBINED BURDEN RELATED TO ENROLLMENT OF OTPS

[Completion of CMS–855B and provider agreement]

	Year 1	Year 2	Year 3	Total	Annualized average over 3-year period
Time (Hours)	5,596	212	209	6,017	2,006
Cost ($)	766,062	29,044	28,612	823,718	274,572

7. The Quality Payment Program (Part 414 and Section III.K. of This Proposed Rule)

a. Background

(1) Information Collection Requirements Associated With MIPS and Advanced APMs

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs.

The ICRs reflect this proposed rule's policies, as well as policies in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and the CY 2019 PFS final rule (83 FR 59452).

(2) Summary of Quality Payment Program Changes: MIPS

As discussed in more detail in section IV.B.7, the MIPS ICRs consist of: Registration for virtual groups; qualified registry self-nomination applications; and QCDR self-nomination applications; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; quality performance category data submission by Medicare Part B claims collection type, QCDR and MIPS CQM collection type, eCQM collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; reweighting applications for Promoting Interoperability and other performance categories; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants.

Two MIPS ICRs show an increase in burden due to proposed changes in policies: QCDR self-nomination applications and Call for Quality Measures. For the QCDR self-nomination applications ICR, we have increased our estimate of the time required to submit a QCDR measure by 1.5 hour due to the proposal to require QCDRs to identify a linkage between their QCDR measures to related cost measures, Improvement Activities, and MIPS Value Pathways starting with the 2021 self-nomination period (+1 hour); and the proposal to require QCDR measure stewards to submit measure testing data as part of the self-nomination process for each QCDR measure (+0.5 hours). For this same ICR, we have increased our estimate of the time required for a QCDR to submit their self-nomination by 0.25 due to the proposal to require QCDRs to include a description of the quality improvement services they intend to support. For the Call for Quality Measures, we have increased our estimate of the time required to nominate a quality measure for consideration by 1 hour due to the proposal to require that MIPS quality measure stewards link their MIPS quality measures to existing and related cost measures and improvement

activities and provide rationale for the linkage. The remaining changes to currently approved burden estimates are adjustments to reflect better understanding of the impacts of policies finalized in previous rules, as well as the use of updated data sources available at the time of publication of this proposed rule. We are not proposing any changes to the following ICRs: Registration for virtual groups, CAHPS survey vendor applications, Quality Payment Program Identity Management Application Process, CAHPS for MIPS survey beneficiary participation, and group registration for CAHPS for MIPS survey. See section IV.B.7.(n) of this proposed rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The revised requirements and burden estimates for all Quality Payment Program ICRs (except for CAHPS for MIPS and virtual groups election) will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The CAHPS for MIPS Survey is approved under OMB control number 0938–1222 (CMS–10450). The Virtual Groups Election is approved under OMB control number 0938–1343 (CMS–10652).

Respondent estimates for the quality, Promoting Interoperability, and improvement activities performance categories are modeled using data from the 2017 MIPS performance period with the sole exception of 104 CMS Web Interface respondents, which is based on the number of groups who submitted data for the quality performance category via the CMS Web Interface for the 2018 MIPS performance period. Although we are using data from the 2017 MIPS performance period as we did in the CY 2019 PFS final rule, our respondent estimates have been updated to reflect revised assumptions regarding QPs and APM participants. Respondent data from the 2018 MIPS performance period was unavailable in time for publication for this proposed rule as was the number of groups and virtual groups registering to submit quality performance category data using the CMS Web Interface. Assuming updated information is available, we intend to update these estimates in the final rule.

Our participation estimates are reflected in Tables 69, 70, and 71 for the quality performance category, Table 87 for the Promoting Interoperability performance category, and Table 92 for the improvement activities performance category.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted due to two primary reasons. First, we anticipate the number of QPs to increase because of total expected growth in Advanced APM participation as new models that are Advanced APMs for which we do not yet have enrollment data become available for participation. The additional QPs will be excluded from MIPS and likely not report. Second, it is difficult to predict what eligible clinicians who may report voluntarily will do in the 2020 MIPS performance period compared to the 2017 MIPS performance period, and therefore, the actual number of participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

(3) Summary of Quality Payment Program Changes: Advanced APMs

As discussed in more detail in sections IV.B.7. of this rule, ICRs for Advanced APMs consist of: Partial Qualifying APM participant (QP) election; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer Combination Option.

For these ICRs, the proposed changes to currently approved burden estimates are adjustments based on updated projections for the 2020 MIPS performance period. We are not proposing any changes to our per-respondent burden estimates. We are also not proposing any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process ICR.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 64 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 64, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 64.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2020 MIPS performance period, the quality data submitted by MIPS APM participants reporting through the CMS Web Interface on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category. For other MIPS APMs, the quality data submitted by APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category if that data is available to be scored. However, as proposed in section III.K.3.c.(5)(c)(i)(A) of this rule, beginning in the 2020 MIPS performance period, MIPS eligible clinicians participating in MIPS APMs whose APM quality data is not available for MIPS may elect to report MIPS quality measures at either the APM entity, individual, or TIN-level in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS quality performance category. If we determine there are not sufficient measures applicable and available, we will assign performance category weights as specified in § 414.1370(h)(5).

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum

improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

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TABLE 64: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Promoting Interoperability Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting MIPS Data [a]	As virtual group, group, or individual clinicians	As virtual group, group, or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As virtual group, group, or individual clinicians	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.
MIPS Eligible Clinicians Participating in MIPS APMs that report via Web Interface	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. If the ACO does not submit quality	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [Burden estimates for	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the MIPS APM.[d]	APM Entities will make Partial QP election for participating MIPS eligible clinicians.

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Promoting Interoperability Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
	data, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[e] [Submissions by the ACO are not included in burden estimates for this proposed rule because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA].[b]	this proposed rule assume group TIN-level reporting].[c]	[The burden estimates for this proposed rule assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.]	
MIPS Eligible Clinicians Participating in Other MIPS APMs	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians; however if the quality data is not available to MIPS in time for scoring, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[e] [Submissions made by APM Entities to MIPS on behalf of their participating MIPS eligible clinicians are not	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this proposed rule assume group TIN-level reporting].	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement	APM Entities will make Partial QP election for participating eligible clinicians.

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
	included in burden estimates for this proposed rule because quality data submission for purposes of testing and evaluating Innovation Center models tested under Section 1115A of the Social Security Act (or Section 3021 of the Affordable Care Act) are not subject to the PRA.]		activity score.]	

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

a Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

b Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

c Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

d APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent.(42 CFR 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

e Both group TIN and individual clinician quality data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. We would then use the highest individual or TIN-level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 PFS final rule and continued in this proposed rule create some additional data collection requirements not listed in Table 64. These additional data collections, some of which were previously approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional Approved ICRs Related to MIPS Third-Party Intermediaries

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).

Additional ICRs Related to the Data Submission and the Quality Performance Category

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related To Call for New MIPS Measures and Activities

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for new quality measures (83 FR 60010 through 60011) (OMB 0938–1314).

Additional ICRs Related to MIPS

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule does not propose any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any virtual group election changes under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as one quality performance category measure, or can be used for completion of an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nominate process annually. The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

The burden associated with qualified registry self-nomination, QCDR self-nomination and measure submission, and the CAHPS for MIPS survey vendor applications follow: [139]

(2) Qualified Registry Self-Nomination Applications

The proposed requirements and burden associated with qualified registries and their self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As explained below, this rule would both adjust the number of self-nomination applications based on current data and revise the number of self-nomination applications due to policies promulgated in the CY 2019 final rule regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) which are effective beginning in the 2020 MIPS performance period. The adjustment would increase our total burden estimates while keeping our burden per response estimates unchanged. We are not proposing changes to the self-nomination process.

We refer readers to § 414.1400(a)(2) and (c)(1) which state that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so.

In the CY 2018 Quality Payment Program final rule and as stated in § 414.1400(c)(1), previously approved qualified registries in good standing (that is, that are not on probation or disqualified) may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period (82 FR 53815). In the same rule, we stated that qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application for CMS review during the self-nomination period (82 FR 53815). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning with the 2020 MIPS performance period (83 FR 59906).

For this proposed rule, we have adjusted the number of self-nominating applicants from 150 to 290 based on more recent data and the assumption that any entity which self-nominated for approval as a QCDR in previous years and that no longer qualifies as a result of policies finalized in the CY 2019 PFS final rule, effective beginning with the 2020 MIPS performance period could elect to self-nominate for approval as a qualified registry. The policies revised both the definition of a QCDR (83 FR 59895) and minimum participation requirements for entities seeking approval as a QCDR (83 FR 59897). Entities which no longer meet the criteria for approval as QCDRs may seek other options such as collaborating with another entity to meet the new requirements or to end their participation in the Quality Payment Program, however, we believe the assumption that these entities will instead elect to self-nominate as a qualified registry is both appropriate and conservative. We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we are making the necessary adjustments to our respondents' estimates in this proposed rule.

For the 2019 MIPS performance period, we received 198 applications for nomination to be a qualified registry, 135 of which were approved to submit data, a reduction of 6 from the currently approved estimate of 141 (83 FR 59997 through 59998). Based on the number of self-nominations received for the 2019 MIPS performance period, we estimate 200 entities will self-nominate as a qualified registry for the 2020 MIPS performance period, not considering

[139] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

nominations from entities which previously qualified as QCDRs. Based on our analysis of the QCDRs approved for the CY 2019 performance period, 63 of the 127 approved QCDRs (49.6 percent) would not meet the criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 181 entities self-nominated for approval as QCDRs, therefore we assume that 90 (49.6 percent) of these entities will self-nominate for approval as qualified registries for the 2020 MIPS performance period. In total, we estimate 290 nomination applications (200 entities + 90 entities) will be received from entities seeking approval to report MIPS data as qualified registries, an increase of 140 from the currently approved estimate of 150 (83 FR 59997 through 59998). As previously stated, this increase is comprised of both an adjustment to due updated data (+50 self-nominations) and a revision due to policies promulgated in the CY 2019 PFS final rule (+90 self-nominations). Assuming updated data is available, we will update our estimates in the final rule to reflect the actual number of nomination applications received for the 2020 MIPS performance period.

The burden associated with the qualified registry self-nomination process varies depending on the number of existing qualified registries that elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The QPP Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938–1314 (CMS–10621).

As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). As shown in Table 66, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor rate of $90.02/hr. Consistent with the CY 2019 PFS final rule (83 FR 59998), we estimate that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry. When considering this rule's adjusted number of nomination applications (290) we estimate that the annual burden will range from 532.5 hours ([135 simplified self-nominations × 0.5 hr] + [155 full self-nominations × 3 hr]) to 870 hours (290 qualified registries × 3 hr) at a cost ranging from $47,936 (532.5 hr × $90.02/hr) to $78,317 (870 hr × $90.02/hr), respectively (*see* Table 66).

As shown in Table 65, compared to the currently approved minimum estimates of 97.5 hours and $8,777 and the maximum estimates of 450 hours and $40,509, the increase in the number of respondents would adjust our total burden estimates by 435 hours and $39,159 [(−6 registries × 0.5 hr × $90.02/hr) + (146 registries × 3 hr × $90.02/hr)] and 420 hours and $37,808 (140 registries × 3 hr × $90.02/hr). While we are proposing to adjust our total burden estimates based on more current data, the burden per response would remain unchanged.

TABLE 65—CHANGE IN ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
Total Annual Hours for Qualified Registries in CY 2019 Final Rule (a)	97.5	450
Total Annual Hours for Qualified Registries in CY 2020 Proposed Rule (b)	532.5	870
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	435	870
Total Annual Cost for Qualified Registries in CY 2019 Final Rule (d)	$8,777	$40,509
Total Annual Cost for Qualified Registries in CY 2020 Proposed Rule (e)	$47,936	$78,317
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$39,159	$37,808

As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088) and in § 414.1400(a)(2), qualified registries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(4)(a)(i) of this rule, beginning with the 2021 performance period and for future years, we propose to require that qualified registries support the reporting of improvement activities and Promoting Interoperability measures in addition to the quality performance category. As finalized in the CY 2017 Quality Payment Program final rule, qualified registries are required to provide feedback on all of the MIPS performance categories at least 4 times a year (81 FR 77367 through 77386). In section III.K.3.g.(4)(a)(ii), we propose, beginning with the 2023 MIPS payment period, to require qualified registries to provide the following as a part of the performance feedback given at least 4 times (to the extent feasible) a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registry. Further, qualified registries will be required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Because we are not requiring qualified registries to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required combined with qualified registries only being required to provide feedback using data they are already collecting, we do not believe the proposal creates enough additional burden for qualified registries to elect to discontinue participation in the Quality Payment Program. Therefore, we are not adjusting our estimates for the number of qualified registries that will self-nominate in the 2021 performance

period or future years as a result of this proposal; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the current self-nomination process, qualified registries are already required to attest to the MIPS quality measures, performance categories, improvement activities, and/or Promoting Interoperability measures and objectives supported. In section III.K.3.g.(4)(a)(i) of this proposed rule, beginning with the 2021 performance period, we are proposing to require qualified registries to support all three performance categories: Quality, improvement activities, and Promoting Interoperability with the proviso that based on the proposed amendment to § 414.1400(a)(2)(iii) the requirement to support submission of Promoting Interoperability data would be inapplicable to the third party intermediary if the clinician, group or virtual group is exempt from this reporting requirement. As part of this proposal, we would require qualified registries to attest to the ability to submit data for all three of these performance categories at time of self-nomination. Because qualified registries will only be required to provide performance feedback to clinicians and not to CMS, and because qualified registries are already required to attest to the performance categories they support, we anticipate minimal changes to the self-nomination process as a result of these proposals and assume there will be minimal impact on the time required to complete either the simplified or full self-nomination process.

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. Therefore, we believe the estimates discussed earlier and shown in Table 66 represents the upper bound for qualified registry burden, with the potential for less additional MIPS burden if the qualified registry already provides similar data submission services.

Based on these assumptions, we estimate the total annual burden associated with a qualified registry self-nominating to be considered for approval.

TABLE 66—ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	135	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	155	290
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Qualified Registries (e) = (a) * (c) + (b) * (d)	532.5	870
Cost Per Simplified Process Per Registry (@computer systems analyst's labor rate of $90.02/hr.) (f)	$45.01	$45.01
Cost Per Full Process Per Registry (@computer systems analyst's labor rate of $90.02/hr.) (g)	$270.06	$270.06
Total Annual Cost for Qualified Registries (h) = (a) * (f) + (b) * (g)	$47,936	$78,317

Both the minimum and maximum burdens shown in Table 66 reflect adjustments to the number of respondents (from 150 to 290) due to availability of more recent data (+50 respondents) and revisions due to policies finalized in the CY 2019 PFS final rule regarding the definition and minimum participation requirements for entities seeking approval as QCDRs which will be effective beginning with the 2020 MIPS performance period (+90 respondents). For purposes of calculating total burden associated with this proposed rule as shown in Table 90, only the maximum burden is being submitted to OMB for their review and approval.

(3) QCDR Self-Nomination Applications

(a) Self-Nomination Process

The proposed requirements and burden associated with QCDRs and the self-nomination process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As explained below, this rule would both adjust the number of self-nomination applications based on current data and revise the number of self-nomination applications due to policies promulgated in the CY 2019 final rule regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) which are effective beginning in the 2020 MIPS performance period. These changes result in a decrease from 200 to 91 self-nomination applications in the 2020 MIPS performance period. This rule would also adjust the number of QCDR measures submitted for consideration by each QCDR seeking to self-nominate (from 9 to 11.5), as well as the time required to submit information (from 1 hour to 2.5 hours) for each QCDR measure. These changes would increase our minimum total burden estimate (from 2,025 hours to 2,729.25 hours) and increase our maximum total burden estimate (from 2,400 hours to 2,889.25 hours). In addition, our per response estimates for the simplified and full self-nomination processes would increase from 9.5 hours to 29.25 hours and from 12 hours to 31.75 hours, respectively.

We refer readers to § 414.1400(a)(2) and (b)(1) which states that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so.

In the CY 2018 Quality Payment Program final rule and § 414.1400(b)(1), previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously

approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the current self-nomination period, from September 1 to November 1 (82 FR 53808). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning in the 2020 MIPS performance period (83 FR 59898).

The burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The OPP Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938–1314 (CMS–10621).

For the 2019 MIPS performance period, we received 181 self-nomination applications from entities seeking approval as QCDRs, 127 of which were approved to submit data. Based on our analysis of the QCDRs approved for the CY 2019 performance period, 63 of the 127 approved QCDRs (49.6 percent) would not meet the criteria for approval for the CY 2020 performance period. We project that 90 (49.6 percent) of the 181 entities will not self-nominate for approval as QCDRs for the 2020 MIPS performance period but will instead self-nominate to be qualified registries. Entities which no longer meet criteria for approval as QCDRs may seek other options as well, including collaborating with another entity to meet the new requirements or to end their participation in the Quality Payment Program; however, we believe the assumption that these entities will instead elect self-nomination as a qualified registry is both appropriate and conservative. We also project the remaining 91 entities will submit nomination applications for approval to report MIPS data as QCDRs for the MIPS 2020 performance period, a decrease of 109 from the currently approved estimate of 200. This decrease of 109 is a result of both an adjustment due to use of more recent data accounts (decrease of 19 self-nominations) and a change due to previously finalized policies regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) (decrease of 90 self-nominations). We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we are making the necessary adjustments to our respondent estimates in this proposed rule. We further estimate that the 64 QCDRs approved to submit data in the 2019 MIPS performance period that would also qualify as QCDRs for the 2020 MIPS performance period will use the simplified self-nomination process. Assuming updated data is available, we will update our estimates in the final rule to reflect the actual number of nomination applications received for the 2020 MIPS performance period.

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(3)(a)(i) of this rule, we are proposing, beginning with the 2021 performance period and future years, to require that QCDRs support three performance categories: Quality, improvement activities, and Promoting Interoperability. We are also proposing in section III.K.3.g.(3)(a)(ii), beginning with the 2023 MIPS payment year and future years, QCDRs would be required to provide services to clinicians and groups to foster improvement in the quality of care provided to patients, by providing educational services in quality improvement and leading quality improvement initiatives and to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. As finalized in the CY 2018 Quality Payment Program final rule, QCDRs are required to provide feedback on all of the MIPS performance categories that the QCDR reports at least 4 times a year (82 FR 53812). In section III.K.3.g.(3)(a)(iii) we propose, beginning with the 2023 MIPS payment year, to require that QCDRs provide the following as a part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. Further, we are also proposing, beginning with the 2023 MIPS payment year, to require QCDRs to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. We do not believe these proposals create enough additional burden for QCDRs to elect to discontinue participation in the Quality Payment Program for multiple reasons: We are not requiring QCDRs to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required, QCDRs will only being required to provide feedback using data they are already collecting, and we are giving QCDRs significant flexibility to provide broad quality improvement services that are tailorable to the specific QCDR and the clinicians they support. Therefore, we are not adjusting our estimates for the number of QCDRs that will self-nominate in the 2021 performance period or future years as a result of this proposal; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the self-nomination process, QCDRs are already required to attest to the MIPS quality measures, performance categories, improvement activities, and Promoting Interoperability measures and objectives supported and will not be required to provide performance feedback to CMS. Therefore, we anticipate no additional steps being added to the self-nomination process as a result of these proposals and assume there will be no impact on the time required to complete either the simplified or full self-nomination process. With regard to the proposal to require QCDRs to describe the quality improvement services they will provide as part of their self-nomination, we estimate this will require approximately 15 minutes to complete.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3.25 hours per QCDR to submit information

required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information.

(b) QCDR Measure Requirements

As promulgated in the CY 2017 and CY 2018 Quality Payment Plan final rules (81 FR 77366 through 77374 and 82 FR 53812 through 53813), QCDRs calculate their measure results and also must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a QCDR will spend an additional 1 hour performing these activities per measure.

As discussed in section III.K.3.g.(3)(c)(i)(B)(cc), we are proposing that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are proposing in section III.K.3.g.(3)(c)(i)(B)(dd) to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. We estimate the time necessary to submit measure testing data as part of the self-nomination process will average approximately 0.5 hours per measure, understanding that this estimate may be either high or low depending on the type of measure and the quantity of data being submitted. We discuss additional impacts of this proposal in section VI.C.10.(f) of this rule's Regulatory Impact Analysis.

In section III.K.3.g.(3)(c)(i)(A)(bb) of this rule, we are proposing to amend § 414.1400 to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we lack insight into both the specific terms and frequency of agreements made between entities, we are not accounting for QCDR measure licensing costs as part of our burden estimate. However, if information regarding the number of licensing agreements and the approximate cost per agreement becomes available, we may adjust our assumptions and burden estimates at that time.

In section III.K.3.g.(3)(c)(i)(B)(cc) of this rule, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for measure harmonization costs as part of our burden estimate, as the process and outcomes of measure harmonization will likely vary substantially depending on a number of factors, including: Extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of this proposed rule, beginning with the 2021 performance period and future years, we are proposing that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measures (as found in section III.K.3.c.(2) of this proposed rule); (b) Improvement Activities (as found in Appendix 2: Improvement Activities Tables); or (c) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of this proposed rule). We estimate that a QCDR will spend an additional 1 hour performing these activities per measure, on average.

We are also proposing to formalize factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2020 performance period and future years. With regard to approving QCDR measures, we are proposing the following: (a) 2-year QCDR measure approval process, and (b) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds. As discussed in section III.K.3.g.(3)(c)(ii)(B) of this rule, we are proposing to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The 2-year approvals would be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: Topped out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this could result in reduced burden for QCDRs as they would not necessarily be required to submit every measure for approval annually. However, because we are

unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the total number of measures that will be submitted for approval and the resulting impact on future burden. If this policy is finalized, the number of QCDR measures submitted in the 2021 performance period will reflect the impact of this policy; at that time we will update our assumptions and burden estimates accordingly.

We estimate that on average, each QCDR will submit information for 11.5 QCDR measures, for a total burden of 11.5 hours per QCDR (1 hr per measure × 11.5 measures). The estimated average of 11.5 measures per QCDR is based on an analysis of the QCDR measures submitted for consideration and QCDR measures approved for the 2019 MIPS performance period, as well as the measures for QCDRs approved for the CY 2019 performance period that would not meet criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 1,123 QCDR measures were submitted for consideration and 762 were approved; an approval rate of 68 percent. Of these approved measures, 264 are for the 63 QCDRs which would not meet criteria for approval for the 2020 MIPS performance period. Averaging the remaining 498 approved QCDR measures by the 64 QCDRs that would meet the criteria for approval for the 2020 MIPS performance period results in approximately 7.8 approved measures per QCDR (498 approved measures / 64 QCDRs). Assuming an identical 68 percent QCDR measure approval rate for measures submitted for consideration for the 2020 MIPS performance period, this results in approximately 11.5 measures submitted for consideration for each QCDR (7.8 approved measures / 0.68 approval rate). We believe the proposals to change requirements for QCDR measure submission and to require QCDRs to harmonize measures we identify as duplicative discussed earlier in this section will result in a reduction in the number of QCDR measures submitted for approval in future years. However, we are unable to quantify the impact these proposed changes will have on the number of measures QCDRs will submit for approval. As information becomes available in future years, we will revisit our assumptions to better reflect the impact of these proposals on QCDRs and the quantity of measures being submitted for consideration annually. When combined with our previously stated assumption regarding our inability to predict which QCDR measures will maintain approval in future years, we believe the estimate of 11.5 measures per QCDR to be both conservative and appropriate, as well as an overall decrease of 76 QCDR measures compared to the 1,123 QCDR measures submitted for consideration in the CY2019 performance period (1,123 QCDR measures − [91 QCDRs × 11.5 measures per QCDR]).

Beginning with the 2021 performance period, we are proposing in section III.K.3.g.(3)(c)(iii) of this proposed rule that in instances where an existing QCDR measure has been in MIPS for 2 years, and has failed to reach benchmarking thresholds due to low adoption, where a QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may develop and submit to a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the proposed criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the total burden associated with this proposal. However, we anticipate the time involved in developing a measure participation plan is likely to average between 1 and 2 hours, depending on the QCDR and the level of detail they choose to include. In future performance periods we may reassess availability of the number of QCDR measure participation plans submitted by QCDRs and estimate the associated burden, if possible. In aggregate, we estimate a QCDR will require 2.5 hours per QCDR measure, an increase of 1.5 hours from the currently approved estimate of 1 hour (83 FR 59999). As discussed earlier in this section, we estimate each QCDR will submit 11.5 QCDR measures for approval, on average. Therefore, we estimate each QCDR will require 28.75 hours (11.5 measures × 2.5 hr per measure) to submit QCDR measures for approval, independent of the selection of the simplified or full self-nomination process.

In the CY 2019 PFS final rule, the burden associated with self-nomination of a QCDR was estimated to range from a minimum of 9.5 hours (0.5 hours to submit information for simplified self-nomination process and 9 hours for submission of QCDR measures) to a maximum of 12 hours (3 hours for the full self-nomination process and 9 hours for the submission of QCDR measures) (83 FR 59999). For this rule, we propose to increase the burden associated with self-nomination to a minimum of 29.25 hours (0.5 hours to submit information for the simplified self-nomination process and 28.75 hours for the submission of QCDR measures) to a maximum of 32 hours (3.25 hours to submit information for the full self-nomination process and 28.75 hours for the submission of QCDR measures) to account for our revised estimate of the average number of QCDR measures submitted for consideration per QCDR, as well as the revised estimate of burden per QCDR measure.

We assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $90.02/hr. Considering that the time per QCDR associated with the self-nomination process ranges from a minimum of 29.25 hours to a maximum of 32 hours, we estimate that the annual burden will range from 2,736 hours ([64 QCDRs × 29.25 hr] + [27 QCDRs × 32 hr]) to 2,912 hours (91 QCDRs × 32 hr) at a cost ranging from $246,295 (2,736 hr × $90.02/hr) and $262,138 (2,912 hr × $90.02/hr), respectively (*see* Table 67).

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 67—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION AND QCDR MEASURE SUBMISSION

	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	64	0
# of QCDR Full Self-Nomination Applications submitted (b)	27	91
Total Annual Hours Per QCDR for Simplified Process (c)	29.25	29.25
Total Annual Hours Per QCDR for Full Process (d)	32.00	32.00

TABLE 67—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION AND QCDR MEASURE SUBMISSION—Continued

	Minimum	Maximum
Total Annual Hours for QCDRs (e) = (a) *(c) + (b) * (d)	2,736	2,912
Cost Per Simplified Process Per QCDR (@computer systems analyst's labor rate of $90.02/hr) (f)	$2,633.09	$2,633.09
Cost Per Full Process Per QCDR (@computer systems analyst's labor rate of $90.02/hr) (g)	$2,880.64	$2,880.64
Total Annual Cost for QCDRs (h) = (a) * (f) + (b) * (g)	$246,295	$262,138

Both the minimum and maximum burden shown in Table 67 reflect adjustments to the number of respondents due to availability of more recent data, as well as changes resulting from policies finalized in the CY 2019 PFS final rule regarding the definition and minimum participation requirements for entities seeking approval as QCDRs which will be effective beginning with the 2020 MIPS performance period. For purposes of calculating total burden associated with the proposed rule as shown in Table 90, only the maximum burden is used.

Independent of the change to our per response time estimate, the decrease in the number of respondents (from 200 to 91) results in an adjustment of between −1,093 hours [(−86 QCDRs × 9.5 hr) + (−23 QCDRs × 12 hr)] at a cost of −$98,392 (−1,093 hr × $90.02) and −1,308 hours (−109 QCDRs × 12 hr) at a cost of −$117,746 (−1,308 hr × $90.02/hr). Accounting for the change in the number of QCDRs, the change in time per QCDR to self-nominate results in an adjustment of 1,820 hours (91 QCDRs × 20 hr) at a cost of $163,836 (1,820 hr × $90.02/hr). As shown in Table 68, when these two adjustments are combined, the net impact ranges between 727 hours (−1,093 hr + 1,820 hr) hours at a cost of $65,444 (−$98,392 + $163,836) and 512 hours (−1,308 hr + 1,820 hr) hours at a cost of $46,090 (−$117,746 + $163,836).

TABLE 68—CHANGE IN ESTIMATED BURDEN FOR QCDR SELF-NOMINATION AND QCDR MEASURE SUBMISSION

	Minimum burden	Maximum burden
Total Annual Hours for QCDRs in CY 2019 Final Rule (a)	2,025	2,400
Total Annual Hours for QCDRs in CY 2020 Proposed Rule (b)	2,736	2,912
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	711	512
Total Annual Cost for QCDRs in CY 2019 Final Rule (d)	$182,291	$216,048
Total Annual Cost for QCDRs in CY 2020 Proposed Rule (e)	$246,295	$262,138
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$64,004	$46,090

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that QCDRs already perform many of these activities for their participants. As stated in section III.K.3.g.(3)(a)(i), based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting these three performance categories. In addition, through our review of previous qualified postings for the 2018 and 2017 MIPS performance periods, we have observed that in 2018, 73 percent (approximately 110 QCDRs) and in 2017, 73 percent (approximately 83 QCDRs) have supported all three of the quality, Promoting Interoperability, and improvement activity performance categories. Given this, we believe it is reasonable that all QCDRs have the capacity to support the improvement activities and Promoting Interoperability performance categories and are not making any further changes to our burden estimates. Therefore, we believe the 2,912-hour estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

(4) CAHPS for MIPS Survey Vendor

This rule does not propose any new or revised collection of information requirements or burden related to CMS-approved CAHPS for MIPS survey vendors. The requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

d. ICRs Regarding Quality Data Submission (§§ 414.1325 and 414.1335)

(1) Background

As explained below, this rule would adjust the number of respondents based on current data. The adjustment would increase our total burden estimates while keeping our ''per response'' estimates unchanged. We are not revising any requirements regarding the number of measures to be submitted or the manner in which they may be submitted.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as MIPS eligible clinicians and those who opt to submit data voluntarily but are not be subject to MIPS payment adjustments.

Clinicians are ineligible for MIPS if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019, that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all partial QPs would participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2020 Medicare QP Performance Period (and therefore would no longer need to submit data to MIPS); hence, our model may under estimate or overestimate the number of respondents.

Using participation data from the 2017 MIPS performance period combined with the estimate of QPs for the 2020 performance period, we estimate a total of 833,243 clinicians will submit quality data as individuals or groups in the 2020 MIPS performance period, a decrease of 131,003 clinicians when compared to our estimate of 964,246 clinicians in the CY 2019 PFS final rule (83 FR 60002). As previously stated in section IV.B.7.(a.(2), respondent data from the 2018 MIPS performance period was unavailable at the time of publication of this proposed rule. Assuming that updated respondent data becomes available before the publication of the CMS–1715–F final rule, we will revise our burden estimates in that rule.

In the CY 2017 Quality Payment Program final rule, we assumed that any clinician that submits quality data codes to us for the Medicare Part B claims collection type is intending to do so for the Quality Payment Program to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504); we continued using this assumption in both the CY 2018 Quality Payment Program final rule and the CY 2019 PFS final rule. In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). However, we also elected to continue using the assumption that all clinicians (except QPs) who submitted data via the Medicare Part B claims collection type in the 2017 MIPS performance period would continue to do so for MIPS to avoid overstating the impact of the change as we lacked the data to accurately estimate both the number of clinicians who would be impacted by the finalized policies and the potential behavioral response of those clinicians who would be required to switch to another collection type (83 FR 60001). For this proposed rule, beginning with the 2020 MIPS performance period, we assume only clinicians in small practices who submitted quality data via Medicare Part B claims in the 2017 MIPS performance period will continue to do so for the 2020 MIPS performance period. Further, we assume that clinicians in other practices (not small practices) who meet at least one of the following criteria will not need to find an alternate collection type for submitting quality performance category data for the Quality Payment Program for the 2020 MIPS performance period: (1) Facility-based; (2) submitted quality data via Medicare Part B claims and at least one other collection type; or (3) were previously scored as part of a group. Finally, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) Scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2017 MIPS performance period. Because we do not have data to accurately predict what collection type each affected clinician would use to collect and report quality data, we assume that the affected clinicians will select the MIPS CQM collection type because, when compared to Medicare Part B claims, we believe this is the next most accessible and least burdensome alternative. Our assumptions result in a 121,858 decrease in the estimated number of clinicians who will submit quality data via Medicare Part B claims and a 15,556 increase in the number of clinicians who will submit via the QCDR/MIPS CQM collection type, as shown in Table 69.

We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. Consistent with assumptions used in the CY 2019 PFS final rule (83 FR 60000 through 60001), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. Therefore, we are not making any adjustments to our respondent estimates as a result of the proposal discussed in section III.K.3.c.(5)(c)(i)(A) of this proposed rule, which allows MIPS eligible clinicians participating in MIPS APMs to elect to report MIPS quality measures at either the individual or TIN-level under the APM scoring standard beginning in the 2020 MIPS performance period. To estimate who will be a MIPS APM participant in the 2020 MIPS performance period, we used the latest 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. If a MIPS eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2017 MIPS performance period. For clinicians who participated in an APM in 2017, were not in an APM in 2019, and did not report MIPS quality data in 2017, we assume they will elect to report to MIPS via the MIPS CQM collection type, similar to our previously stated assumption regarding clinicians who are required to use an alternate reporting option. In addition, we assume that the 80 TINs that elect to form 16 virtual groups will continue to collect and submit MIPS data using the same collection and submission types as they did during the 2017 MIPS performance period, but the submission will be at the virtual group, rather than group level.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[140] Tables 69, 70, and 71 explain our

[140] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 69 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2020 MIPS performance period based on data from the 2017 MIPS performance period.

For the 2020 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and CMS Web Interface. We estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created using the Identity Management Application Process, registration is not required again for future years.

Table 69 shows that in the 2020 MIPS performance period, an estimated 109,951 clinicians will submit data as individuals for the Medicare Part B claims collection type; 359,621 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 247,329 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 116,342 clinicians will submit as part of groups via the CMS Web Interface.

Table 69 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 69—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2020 MIPS performance period (excludes QPs) (a)	109,951	359,621	247,329	116,342	833,243
* Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2019 MIPS performance period (excludes QPs) (b)	257,260	324,693	243,062	139,231	964,246
Difference between 2020 MIPS performance period (CY 2020 Proposed Rule) and 2019 MIPS performance period (CY 2019 Final Rule) (c) = (a) − (b)	−147,309	34,928	4,267	−22,889	−131,003

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allowed MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, with the exception of clinicians not in small practices who previously submitted quality data via Medicare Part B claims, we captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the 2017 MIPS performance period.

Table 70 uses methods similar to those described to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2020 MIPS performance period. We estimate that approximately 109,951 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 106,039 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,455 clinicians will submit data as individuals using eCQMs collection type.

TABLE 70—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of Clinicians to submit data as individuals in 2020 MIPS Performance Period (excludes QPs) (a)	109,951	106,039	47,455	0	263,445
* Number of Clinicians to submit data as individuals in 2019 MIPS Performance Period (excludes QPs) (b)	257,260	71,439	47,557	0	376,256

TABLE 70—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE—Continued

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Difference between 2020 MIPS Performance Period (CY 2020 proposed rule) and 2019 MIPS performance period (CY 2019 final rule) (c) = (a) − (b)	−147,309	+34,600	−102	0	−112,811

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 70 are not mutually exclusive.

Table 71 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2020 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. With the previously discussed exceptions regarding groups who experienced a change in APM participation status between the 2017 and 2019 MIPS performance periods, we assume that groups that submitted quality data as groups in the 2017 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2020 MIPS performance period. First, we estimated the number of groups or virtual groups that will collect data via each collection type during the 2020 MIPS performance period using data from the 2017 MIPS performance period. The second and third steps in Table 71 reflect our currently approved assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations that will submit quality data on behalf of clinicians. We assume that 40 groups that previously collected on behalf of clinicians via QCDR or MIPS CQM collection types will elect to form 8 virtual groups that will collect via QCDR and MIPS CQM collection types. We assume that another 40 groups that previously collected on behalf of clinicians via eCQM collection types will elect to form another 8 virtual groups that will collect via eCQM collection types. Hence, the second step in Table 71 is to subtract out the estimated number of groups under each collection type that will elect to form virtual groups, and the third step in Table 71 is to add in the estimated number of virtual groups that will submit on behalf of clinicians for each collection type.

Specifically, we assume that 10,552 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,582 clinicians; 4,332 groups and virtual groups will submit for eCQM collection types on behalf of 199,874 eligible clinicians; and 104 groups will submit data via the CMS Web Interface on behalf of 116,342 clinicians.

TABLE 71—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in 2020 MIPS performance period (excludes QPs) (a)	0	10,584	4,364	104	15,052
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period (c)	0	8	8	0	16
Number of groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period (d) = (a) − (b) + (c)	0	10,552	4,332	104	14,988
* Number of groups to collect data by collection type on behalf of clinicians in 2019 MIPS performance period (e)	0	10,542	4,304	286	15,132
Difference between 2020 MIPS performance period (CY 2020 proposed rule) and 2019 MIPS performance period (CY 2019 final rule) (f) = (d) − (e)	0	10	28	−182	−144

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary

along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2020 MIPS performance period, the total number of quality measures will be 206. The new MIPS quality measures proposed for inclusion in MIPS for the 2020 MIPS performance period and future years are found in Table Group A of Appendix 1; MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 72, as well as counts of new, removed, and substantively changed measures.

TABLE 72—SUMMARY OF QUALITY MEASURES FOR THE 2020 MIPS PERFORMANCE PERIOD

Collection type	Number measures proposed as new	Number measures proposed for removal	Number measures proposed with a substantive change *	Number measures remaining for CY 2020
Medicare Part B Claims Specifications	0	17	22	47
MIPS CQMs Specifications	3	52	77	184
eCQM Specifications	1	6	33	45
Survey—CSV	0	0	0	1
CMS Web Interface Measure Specifications	1	1	9	10
Administrative Claims	0	0	0	1
Total **	4	55	95	206

* This column includes all measures that have a requested substantive change from the measure stewards. The total of 95 substantive changes reflects both measures that will continue and a subset of measures that have been proposed for removal for PY2020. There are 73 substantive changes that are proposed in Appendix 1 for measures not being proposed for removal.

** A measure may be specified under multiple collection types but will only be counted once in the total.

For the 2020 MIPS performance period, there is a net reduction of 51 quality measures across all collection types compared to the 257 measures finalized for the 2019 MIPS performance period (83 FR 60003). We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups as respondents are still required to submit quality data for 6 measures. Likewise, we do not anticipate a change in reporting burden as a result of the one proposed administrative claims measure (The All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure) which is being proposed for the 2021 MIPS performance period as discussed in section III.K.3.c.(1)(d)(ii) of this rule.

As discussed in section III.K.3.c.(1)(c)(ii) of this rule, we are proposing to adopt a higher data completeness threshold (the percentage of eligible patients the clinician must check to see whether the measure applies to) for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMs must submit data on at least 70 percent of the MIPS eligible clinician or group's patients that meet the denominator criteria, regardless of payer for the 2020 MIPS performance period. We believe this proposal may increase administrative burden for some clinicians as it affects the amount of data they have to collect, but will have no impact on regulatory burden as it affects neither the number of quality measures they are required to report nor the amount of data they must report for each quality measure once results have been aggregated.

(2) Quality Payment Program Identity Management Application Process

This rule does not propose any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any identity management application process changes under that control number.

(3) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule does not propose any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Table 69, based on 2017 MIPS performance period data, we assume that 109,951 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule proposes to adjust the number of Medicare Part B claims respondents from 257,260 to 109,951 (a decrease of 147,309) based on more recent data and our updated methodology of accounting only for clinicians in small practices who submitted such claims data in the 2017 MIPS performance period rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type. We continue to anticipate that the Medicare Part B claims submission process for MIPS is operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to

gather the required information, select the appropriate QDCs, and include the appropriate QDCs on the Medicare Part B claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197. This proposed rule's provisions do not necessitate the revision of either form and we are making no changes to the associated estimate of reporting burden.

As shown in Table 73, consistent with our currently approved per respondent burden estimates, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours at a cost of $13.50 (0.15 hr × $90.02/hr) to 7.2 hours at a cost of $648.14 (7.2 hr × $90.02/hr) per respondent. The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $45.24/hr for an LPN/medical assistant, 1 hour at $90.02/hr for a computer systems analyst, and 1 hour at $38.00/hr for a billing clerk. We are not proposing revisions to our currently approved per response burden estimates.

The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of Medicare Part B claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time ranges from 786,150 hours (7.15 hr × 109,951 clinicians) to 1,561,304 hours (14.2 hr × 109,951 clinicians). The estimated annual cost (per clinician) ranges from $717.70 [(0.15 hr × $90.02/hr) + (3 hr × $109.36/hr) + (1 hr × $90.02/hr) + (1 hr × $45.24/hr) + (1 hr × $38.00/hr + (1 hr × $202.86/hr)] to a maximum of $1,352.34 [(7.2 hr × $90.02/hr) + (3 hr × $109.36/hr) + (1 hr × $90.02/hr) + (1 hr × $45.24/hr) + (1 hr × $38.00/hr + (1 hr × $202.86/hr)]. The total annual cost ranges from a minimum of $78,912,163 (109,951 clinicians × $717.70) to a maximum of $148,691,575 (109,951 clinicians × $1,352.34).

Table 73 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

TABLE 73—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden
# of Clinicians (a)	109,951	109,951	109,951
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	786,150	885,106	1,561,304
Cost to Submit Quality Data (@computer systems analyst's labor rate of $90.02/hr) (j)	$13.50	$94.52	$648.14
Cost to Review Measure Specifications (@practice administrator's labor rate of $109.36/hr) (k)	$328.08	$328.08	$328.08
Cost to Review Measure Specifications (@computer systems analyst's labor rate of $90.02/hr) (l)	$90.02	$90.02	$90.02
Cost to Review Measure Specifications (@LPN's labor rate of $45.24/hr) (m)	$45.24	$45.24	$45.24
Cost to Review Measure Specifications (@billing clerk's labor rate of $38.00/hr) (n)	$38.00	$38.00	$38.00
Cost to Review Measure Specifications (@physician's labor rate of $202.86/hr) (o)	$202.86	$202.86	$202.86
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$717.70	$798.72	$1,352.34
Total Annual Cost (q) = (a) * (p)	$78,912,163	$87,820,173	$148,691,575

As shown in Table 74, using the unchanged currently approved per respondent burden estimates which range from $717.70 to $1,352.34, the decrease in number of respondents from 257,260 to 109,951 results in a total adjustment of between −1,053,259 hours (−147,309 respondents × 7.15 hr/respondent) at a cost of −$105,724,111 (−147,309 respondents × $717.70/respondent) and −2,091,788 hours (−147,309 respondents × 14.2 hr/respondent) at a cost of −$199,212,442 (−147,309 respondents × $1,352.34/respondent).

TABLE 74—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,839,409	2,070,943	3,653,092
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	786,150	885,106	1,561,304

TABLE 74—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE—Continued

	Minimum burden	Median burden	Maximum burden
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−1,053,259	−1,185,837	−2,091,788
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$184,636,274	$205,478,964	$347,904,017
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$78,912,163	$87,820,173	$148,691,575
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$105,724,111	−$117,658,791	−$199,212,442

(4) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

This rule does not propose any new or revised collection of information requirements related to the MIPS CQM or QCDR collection types. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 69, 70, and 71, and based on 2017 MIPS performance period data, we assume that 359,621 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 106,039 clinicians, as shown in Table 70, will submit as individuals and 10,552 groups and virtual groups, as shown in Table 71, are expected to submit on behalf of the remaining 253,582 clinicians. As previously stated, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) Scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2017 MIPS performance period. As a result of this assumption and our use of more recent data, this rule proposes to adjust the number of QCDR and MIPS CQM respondents from 81,981 to 116,591 (an increase of 34,610). Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS collection requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $872.37 per individual clinician or group. This consists of 3 hours at $90.02/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $109.36/hr for a practice administrator, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for a LPN/medical assistant, 1 hour at $38.00/hr for a billing clerk, and 1 hour at $202.86/hr for a clinician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a cost of $7.50 (0.083 hr × $90.02/hr for a computer systems analyst).

In aggregate, we estimate an annual burden of 1,058,996 hours (9.083 hr/response × 116,591 groups plus clinicians submitting as individuals) at a cost of $101,710,684 (116,591 responses × $872.37/response). The increase in number of respondents from 81,981 to 116,591 results in a total adjustment of 314,363 hours (34,610 respondents × 9.083 hr/respondent) at a cost of $30,192,783 (34,610 respondents × $872.37/respondent). Based on these assumptions, we have estimated in Table 75 the burden for these submissions.

TABLE 75—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
# of clinicians submitting as individuals (a)	106,039
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,552
# of Respondents (groups plus clinicians submitting as individuals) (c) = (a) + (b)	116,591
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinician Review Measure Specifications (i)	1

TABLE 75—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE—Continued

	Burden estimate
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k) = (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c) * (k)	1,058,996
Cost Per Respondent to Submit Quality Data (@computer systems analyst's labor rate of $90.02/hr) (m)	$270.06
Cost to Review Measure Specifications (@practice administrator's labor rate of $109.36/hr) (n)	$218.72
Cost Computer System's Analyst Review Measure Specifications (@computer systems analyst's labor rate of $90.02/hr) (o)	$90.02
Cost LPN Review Measure Specifications (@LPN's labor rate of $45.24/hr) (p)	$45.24
Cost Billing Clerk Review Measure Specifications (@clerk's labor rate of $38.00/hr) (q)	$38.00
Cost Clinician Review Measure Specifications (@physician's labor rate of $202.86/hr) (r)	$202.86
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@computer systems analyst's labor rate of $90.02/hr) (s)	$7.50
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$872.37
Total Annual Cost (u) = (c) * (t)	$101,710,684

As shown in Table 76, using the unchanged currently approved per respondent burden estimate, the increase in number of respondents from 81,981 to 116,591 results in a total difference of 314,363 hours (34,610 respondents × 9.083 hr/respondent) at a cost of $30,192,783 (34,610 respondents × $872.37/respondent).

TABLE 76—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	744,633
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	1,058,996
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	314,363
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$71,517,901
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$101,710,684
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$30,192,783

(5) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

This rule does not propose any new or revised collection of information requirements related to the eCQM collection type. However, we are proposing to adjust our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 69, 70, and 71, based on 2017 MIPS performance period data, we assume that 247,329 clinicians will elect to use the eCQM collection type; 47,455 clinicians are expected to submit eCQMs as individuals; and 4,332 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 199,874 clinicians. This rule proposes to adjust the number of eCQM respondents from 51,861 to 51,787 (a decrease of 74) based on more recent data. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to the CMS-designated clinical data warehouse.

We estimate that it will take no more than 2 hours at $90.02/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS submission. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for

a LPN/medical assistant, and 1 hour at $38.00/hr for a billing clerk.

In aggregate we estimate an annual burden of 414,296 hours (8 hr × 51,787 groups and clinicians submitting as individuals) at a cost of $40,128,711 (51,787 responses × $774.88/response). Based on these assumptions, we have estimated in Table 77 the burden for these submissions.

TABLE 77—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
# of clinicians submitting as individuals (a)	47,455
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,332
# of Respondents (groups and clinicians submitting as individuals) (c) = (a) + (b)	51,787
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	414,296
Cost Per Respondent to Submit Quality Data (@computer systems analyst's labor rate of $90.02/hr) (l)	$180.04
Cost to Review Measure Specifications (@practice administrator's labor rate of $109.36/hr) (m)	$218.72
Cost to Review Measure Specifications (@computer systems analyst's labor rate of $90.02/hr) (n)	$90.02
Cost to Review Measure Specifications (@LPN's labor rate of $45.24/hr) (o)	$45.24
Cost to Review Measure Specifications (@clerk's labor rate of $38.00/hr) (p)	$38.00
Cost to D21Review Measure Specifications (@physician's labor rate of $202.86/hr) (q)	$202.86
Total Cost Per Respondent (r) = (l) + (m) + (n) + (o) + (p) + (q)	$774.88
Total Annual Cost (s) = (c) * (r)	$40,128,711

As shown in Table 78, using the unchanged currently approved per respondent burden estimate, the decrease in number of respondents from 51,861 to 51,787 results in a total difference of −592 hours (−74 respondents × 8 hr/respondent) at a cost of −$57,341 (−74 respondents × $774.88/respondent).

TABLE 78—CHANGE IN ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	414,888
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	414,296
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−592
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$40,186,052
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$40,128,711
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$57,341

(6) Quality Data Submission via CMS Web Interface

This rule does not propose any new or revised collection of information requirements related to submission of quality data via the CMS Web Interface. However, we are proposing adjustments to our currently approved burden estimates based on more recent data. The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We assume that 104 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the 2018 MIPS performance period. This is a decrease of 182 groups from the currently approved number of 286 groups provided in the CY 2019 PFS final rule (83 FR 60007) due to receipt of more current data. We estimate that 116,342 clinicians will submit as part of groups via this method, a decrease of 22,889 from our currently approved estimate of 139,231 clinicians.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Our burden estimate for submission includes the time (61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into

the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate an annual burden of 6,414 hours (104 groups × 61.67 hr) at a cost of $577,359 (6,414 hr × $90.02/hr). Based on the assumptions discussed in this section, Table 79 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 79—ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
# of Eligible Group Practices (a)	104
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a) * (b)	6,414
Cost Per Group to Report (@computer systems analyst's labor rate of $90.02/hr.) (d)	$5,551.53
Total Annual Cost (e) = (a) * (d)	$577,359

As shown in Table 80, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −11,224 hours (−182 respondents × 61.67 hr) at −$1,010,379 (−11,224 hr × $90.02/hr).

TABLE 80—CHANGE IN ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	17,637
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	6,413
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−11,224
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,587,739
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$577,359
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$1,010,379

(7) Beneficiary Responses to CAHPS for MIPS Survey

This rule does not propose any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

(8) Group Registration for CMS Web Interface

This rule does not propose any new or revised collection of information requirements related to the group registration for CMS Web Interface. However, we propose to adjust our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 81, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $90.02/hr for a computer systems analyst (or their equivalent) to register the group.

In this rule, we propose to adjust the number of respondents from 67 to 51 based on more recent data. We assume that approximately 51 groups will elect to use the CMS Web Interface for the first time during the 2020 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; a decrease of 16 compared to the number of groups currently approved by OMB. The registration period for the CY 2019 MIPS performance period ends on June 30, 2019; assuming updated information is available, we will update our respondent estimates in the final rule. As shown in Table 81, we estimate a burden of 12.75 hours (51 new registrations × 0.25 hr/registration) at a cost of $1,148 (12.75 hr × $90.02/hr).

TABLE 81—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE

	Burden estimate
Number of New Groups Registering for CMS Web Interface (a)	51
Annual Hours Per Group (b)	0.25

TABLE 81—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE—Continued

	Burden estimate
Total Annual Hours (c) = (a) * (b)	12.75
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a) * (d)	$1,148

As shown in Table 82 using our unchanged currently approved per respondent burden estimates, the decrease in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 4 hours at a cost of $360 (−16 groups × 0.25 hr × $90.02/hr).

TABLE 82—CHANGE IN ESTIMATED BURDEN FOR GROUP REGISTRATIONS FOR THE CMS WEB INTERFACE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	16.75
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	12.75
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−4
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,508
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$1,148
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$360

(9) Group Registration for CAHPS for MIPS Survey

This rule does not propose any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, are not making any MIPS survey vendor changes under that control number.

e. ICRs Regarding the Nomination of Quality Measures

The proposed requirements and burden associated with this data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the **Federal Register** by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a ''Call for Quality Measures'' each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html.*

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, a gap analysis which includes evidence for the measure, reliability, validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form. As discussed in section III.K.3.c.(1)(d)(i) of this rule, we are proposing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards would also be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities. We believe this would require approximately 0.6 hours at $109.36/hr for a practice administrator and 0.4 hours at $202.86 for a clinician to research existing measures or activities and provide a rationale for the linkage to the new measure. We also estimate it would require 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $202.86/hr for clinician review time. We recognize there is additional burden on respondents associated with development of a new quality measure beyond the 1.5 hour estimate (0.6 hr + 0.4 hr + 0.3 hr + 0.2 hr) which only accounts for the time required for recordkeeping, reporting, and third-party disclosures associated with the policy; but we believe this estimate to be reasonable to nominate and submit a measure. The 1.5 hour estimate also assumes that submitters will have the necessary information to complete the nomination form readily available,

which we believe is a reasonable assumption. Additionally, some submitters familiar with the process or who are submitting multiple measures may require significantly less time, while other submitters may require more if the opposite is true. Representing an average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate the measure, we believe the total estimate of 1.5 hours per measure to be reasonable and appropriate.

As shown in Table 83, we estimate that 26 submissions will be received during the 2019 Call for Quality Measures based on the number of submissions received during the 2018 Call for Quality Measures process; a decrease of 114 compared to the number of submissions currently approved by OMB (140 submissions). The 2019 Call for Quality Measures process ends on June 3, 2019; assuming updated information is available, we will update our estimate in the final rule. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $202.86/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption.

As shown in Table 83, in aggregate we estimate an annual burden of 143 hours (26 submissions × 5.5 hr/submission) at a cost of $26,821 {26 submissions × [(0.9 hr × $109.36/hr) + (4.6 hr × $202.86/hr}.

TABLE 83—ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	26
# of Hours Per Practice Administrator to Identify, Propose, and Link Measure (b)	0.9
# of Hours Per Clinician to Identify and Link Measure (c)	0.6
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e) = (b) + (c) + (d)	5.50
Total Annual Hours (f) = (a) * (e)	143
Cost to Identify and Submit Measure (@practice administrator's labor rate of $109.36/hr.) (g)	$98.42
Cost to Identify Quality Measure and Complete Peer Review Article Form (@physician's labor rate of $202.86/hr.) (h)	$933.16
Total Annual Cost Per Respondent (i) = (g) + (h)	$1,031.58
Total Annual Cost (j) = (a) * (i)	$26,821

Independent of the decrease in the number of new quality measures submitted for consideration, the increase in burden per nominated measure results in a difference of 140 hours at a cost of $20,546 {140 submissions × [(0.6 hr × $109.36/hr) + (0.4 hr × $202.86/hr)]}. The decrease in the number of new quality measures submitted results in an adjustment of −627 hours at −$117,600 (−114 submissions × [(0.9 hr × $109.36/hr) + (4.6 hr × $202.86/hr)]). As shown in Table 84, in aggregate, the combine impact of these changes is −487 hours (140 − 627) at a cost of −$97,054 ($20,546 − $117,600).

TABLE 84—CHANGE IN ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	630
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	143
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−487
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$123,875
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$26,821
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$97,054

f. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the 2020 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting

the quality data submission will also support the Promoting Interoperability data submission process. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category via a qualified registry or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type. The proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories would alleviate this issue. Hence, the following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

This rule does not propose any new or revised collection of information requirements related to the submission of reweighting applications for Promoting Interoperability and other performance categories. However, we propose to adjust our currently approved burden estimates based on an updated analysis of individuals and groups who submitted reweighting applications for the 2017 MIPS performance period but likely would not submit such applications for the 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances: Insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, clinicians who are in a small practice, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686, respectively). In addition, in the CY 2018 Quality Payment Program final rule, we established that MIPS eligible clinicians and groups citing extreme and uncontrollable circumstances may also apply for a reweighting of the quality, cost, and/or improvement activities performance categories (82 FR 53783 through 53785). As discussed in section III.K.3.d.(2)(b)(ii)(A), we are proposing, beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to reweight the performance categories for a MIPS eligible clinician who we determine has data for a performance category that are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician or its agents if we learn the relevant information prior to the beginning of the associated MIPS payment year. Because this is a new policy and we believe these occurrences are rare based on our experience, we are unable to estimate the number of clinicians, groups, or third party intermediaries that may contact us regarding a potential data issue. Similarly, the extent and source of documentation provided to us for each event may vary considerably. Therefore, we are not proposing any changes to our currently approved burden estimates as a result of this proposal. Respondents who apply for a reweighting for any of these performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications. Data on the number of reweighting applications submitted for the 2018 MIPS performance period is unavailable for this proposed rule. Assuming updated information is available for the final rule, we will assess the utility of using this information to estimate burden for future performance periods and will make a determination at that time as to the most appropriate data to use in estimating future burden.

Table 85 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received for the 2017 MIPS performance period, we assume 6,025 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification. Of that amount we estimate that 3,365 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 2,660 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We estimate it would take 0.25 hours at $90.02/hr for a computer system analyst to complete and submit the application. As shown in Table 85, we estimate an annual burden of 1,506.25 hours (6,025 applications × 0.25 hr/application) at a cost of $135,593 (1,506.25 hr × $90.02/hr).

TABLE 85—ESTIMATED BURDEN FOR REWEIGHTING APPLICATIONS FOR PROMOTING INTEROPERABILITY AND OTHER PERFORMANCE CATEGORIES

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions (a)	3,365
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	2,660
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	6,025
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	1,506.25
Labor Rate for a computer systems analyst (f)	$90.02/hr
Total Annual Cost (g) = (a) * (f)	$135,593

As shown in Table 86, using our unchanged currently approved per respondent burden estimate, the decreased number of respondents results in a total adjustment of −4 hours (−16 respondents × 0.25 hr/respondent) and −$360 (−16 respondents × $22.50/respondent).

TABLE 86—CHANGE IN ESTIMATED BURDEN FOR REWEIGHTING APPLICATIONS FOR PROMOTING INTEROPERABILITY AND OTHER PERFORMANCE CATEGORIES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,510
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	1,506
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−4
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$135,953
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$135,593
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$360

(3) Submitting Promoting Interoperability Data

This rule does not propose any new or revised collection of information requirements related to the submission of Promoting Interoperability data. However, we propose to adjust our currently approved burden estimates based on updated estimates of QPs and MIPS APMs for 2019 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264) and CY 2019 PFS final rule (83 FR 59822–59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group.

As shown in Table 87, based on data from the 2017 MIPS performance period, we estimate that a total of 93,863 respondents consisting of 81,358 individual MIPS eligible clinicians and 12,505 groups and virtual groups will submit Promoting Interoperability data. Similar to the process shown in Table 71 for groups reporting via QCDR/MIPS CQM and eCQM collection types, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period.

Because our respondent estimates are based on the number of actual submissions received for the Promoting Interoperability performance category, it is not necessary to account for policies adopted in the CY 2017 Quality Payment Program final rule regarding reweighting, which state that if a clinician submits Promoting Interoperability data, they will be scored and the performance category will not be reweighted (81 FR 77238–77245). This approach is identical to the approach we used in the CY 2019 PFS final rule (83 FR 60013 through 60014), however we failed to state the distinction in that final rule that we no longer need to make modifications to our estimates due to the use of actual MIPS submission data. As established in the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019 PFS final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists; occupational therapists; qualified speech-language pathologists or qualified audiologist; clinical psychologists; and registered dieticians or nutrition professionals (81 FR 77238 through 77245, 82 FR 53680 through 53687, and 83 FR 59819 through 59820, respectively). For the same reasons discussed above regarding our use of data reflecting the actual number of Promoting Interoperability data submissions received, these estimates already account for the reweighting policies in the CY 2017 and CY 2018 Quality Payment Program final rules,

including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR (81 FR 77240 through 77243 and 82 FR 53680 through 53686).

In section III.K.3.c.(4)(f)(iii), we propose to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We propose that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We also propose to revise § 414.1380(c)(2)(iii) to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician or the definition of a non-patient facing MIPS eligible clinician as defined in § 414.1305. We believe these proposals could result in a decrease in the number of data submissions for the Promoting Interoperability performance category, but we do not currently have the data necessary to determine how many groups would elect to forego submission. As additional information becomes available in future years, we will revisit the impact of this policy and adjust our burden estimates accordingly.

As discussed in section III.K.3.c.(4)(d)(i)(B) of this rule, we propose to allow clinicians to satisfy the optional bonus Query of PDMP measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. In the CY 2019 PFS final rule, we updated our burden assumptions from 3 hours to 2.67 hours to reflect the change from 5 base measures, 9 performance measures, and 4 bonus measures to the reporting of 4 base measures (83 FR 60013 through 60014). Due to a lack of data regarding the number of health care providers who would submit data for bonus Promoting Interoperability measures, we have consistently been unable to estimate burden related to the reporting of bonus measures and are therefore unable to account for any change in burden due to the proposed change to a ''yes/no'' attestation for the Query of PDMP measure. If we have better data in the future, we may reassess our burden assumptions and whether we can reasonably quantify the burden associated with the reporting of bonus measures.

We assume that MIPS eligible clinicians scored under the APM scoring standard, as described in section III.K.3.c.(5)of this rule, would continue to submit Promoting Interoperability data the same as in 2017. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. In the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822–59823). Burden estimates for this proposed rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TIN as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

TABLE 87—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Number of respondents
Number of individual clinicians to submit Promoting Interoperability (a)	81,358
Number of groups to submit Promoting Interoperability (b)	12,569
Subtract: Number of groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (c)	80
Add in: Number of virtual groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period (d)	16
Number of groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period (e) = (b) − (c) + (d)	12,505
Total Respondents in 2020 MIPS performance period (CY 2020 Proposed Rule) (f) = (a) + (e)	93,863
*Total Respondents in 2019 MIPS performance period (CY 2019 Final Rule) (g)	93,869
Difference between CY 2020 Proposed Rule and CY 2019 Final Rule (h) = (f) − (g)	−6

We estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As previously discussed, beginning with the 2021 performance period and for future years, we propose to require that QCDRs and qualified registries support three performance categories: Quality, improvement activities, and Promoting Interoperability. Based on our review of 2019 qualified registries and QCDRs, we have determined that 70 percent and 72 percent of these vendors, respectively, already support reporting for these performance categories. For clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data, we believe this would result in a reduction of burden as it would simplify MIPS reporting. In order to estimate the impact on reporting burden, we would need to correlate the specific individual clinicians and groups who submitted quality performance category data via the MIPS CQM/QCDR collection type that are required to report data for both the quality and Promoting Interoperability performance categories

with the specific qualified registries or QCDRs that are affected by this proposal. Currently, we do not have the necessary information to perform this correlation and are therefore unable to estimate the resulting impact on burden. If data becomes available in the future which enables us to perform this analysis, we will update our burden estimates at that time.

As shown in Table 88, the total burden estimate for submission of data on the specified Promoting Interoperability objectives and measures is estimated to be 250,301 hours (93,853 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of $22,532,126 (250,301 hr × $90.02/hr).

TABLE 88—ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Number of individual clinicians to submit Promoting Interoperability (a)	81,358
Number of groups to submit Promoting Interoperability (b)	12,505
Total (c) = (a) + (b)	93,863
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a) * (b)	250,301
Labor rate for a computer systems analyst to submit Promoting Interoperability data (d)	$90.02/hr
Total Annual Cost (e) = (a) * (d)	$22,532,126

As shown in Table 89, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −16 hours (−6 respondents × 2.67 hr/respondent) at a cost of −$1,440 (−16 hr × $90.02/hr).

TABLE 89—CHANGE IN ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	250,317
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	250,301
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−16
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$22,533,566
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$22,532,126
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$1,440

g. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule does not propose any new or revised collection of information requirements related to the nomination of Promoting Interoperability measures. However, we propose to adjusted our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Consistent with our requests for stakeholder input on quality measures and improvement activities, we also request potential measures for the Promoting Interoperability performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via the Call for Promoting Interoperability Performance Category Measures Submission Form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable). This rule does not propose any changes to that form.

We estimate 28 proposals will be submitted for new Promoting Interoperability measures, based on the number of proposals submitted during the CY 2018 nomination period. This is a decrease of 19 from the estimate currently approved by OMB (47 proposals) under the aforementioned control number. The 2019 Call for Promoting Interoperability Measures process ends on July 1, 2019; assuming updated information is available, we will update our estimate in the final rule. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $202.86/hr for a clinician to review the nomination. As shown in Table 90, we estimate an annual burden of 14 hours (28 proposals × 0.5 hr/response) at a cost of $2,055 (28 × [(0.3 hr × $109.36/hr) + (0.2 hr × $202.86/hr)].

TABLE 90—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
# of Promoting Interoperability Measure Nominations (a)	28
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) * (d)	14
Cost to Identify and Submit Measure (@practice administrator's labor rate of $109.36/hr) (f)	$32.81
Cost to Identify Improvement Measure (@physician's labor rate of $202.86/hr) (g)	$40.57
Total Annual Cost Per Respondent (h) = (f) + (g)	$73.38
Total Annual Cost (i) = (a) * (h)	$2,055

As shown in Table 91, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −9.5 hours at a cost of −$1,394 (−19 respondents × 0.5 hr × $73.38 per respondent).

TABLE 91—CHANGE IN ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	23.5
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	14
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−9.5
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$3,449
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$2.055
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$1,394

h. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

This rule does not propose any new or revised collection of information requirements related to the submission of Improvement Activities data. However, we propose to adjust our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.K.3.c.(3)(d)(iii) of this rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. Because eligible clinicians are able to attest to improvement activity measures at the group level, there is no impact on reporting burden as a result of this proposal.

As previously discussed, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability; our discussion of burden for submitting Promoting Interoperability data in section IV.B.7.(f).(3) noted our inability to account for the reduction in burden associated with the proposal. Consistent with our decision not to change our per respondent burden estimate to submit Promoting Interoperability data, we are not changing our per respondent burden estimate to submit improvement activity data as a result of this proposal.

Furthermore, as discussed in section III.K.3.c.(3)(e)(i) of this rule, we are proposing to establish removal factors to consider when proposing to remove improvement activities from the Inventory. However, we do not believe this would affect reporting burden, because respondents would still be required submit the same number of improvement activities and this proposal would not require respondents to submit any additional information. We are also proposing for the CY 2020 performance period and future years to: Add 2 new improvement activities, modify 7 existing improvement activities, and remove 15 existing improvement activities. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these proposals to affect our currently approved burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty practice, the eligible clinician or group must attest in the same manner as any other improvement activity.

While our proposals do not add additional reporting burden, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2018 Quality Payment Program final rule provides: (1) That for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a ''yes'' response

for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term ''recognized'' is accepted as equivalent to the term ''certified'' when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we described how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, based on our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities. We anticipate that MIPS APMs in the 2019 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category through a MIPS CQM or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type, the proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories would help to alleviate this issue. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 92, based on 2017 MIPS performance period data, we estimate that 102,754 clinicians will submit improvement activities as individuals during the 2020 MIPS performance period and 15,761 groups will submit improvement activities on behalf of clinicians. Similar to the process shown in Table 87 for groups submitting Promoting Interoperability data, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period. In addition, as previously discussed regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we have updated our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or members of an APM in the 2017 MIPS performance period but will be in the 2019 MIPS performance period, and would therefore not be required to submit improvement activities data.

Our burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM Entity level. We also assume that the MIPS APM models for the 2020 MIPS performance period will qualify for the maximum improvement activities performance category score and, as such, APM Entities will not submit any additional improvement activities.

TABLE 92—ESTIMATED NUMBERS OF ORGANIZATIONS SUBMITTING IMPROVEMENT ACTIVITIES PERFORMANCE CATEGORY DATA ON BEHALF OF CLINICIANS

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2020 MIPS performance period (a)	102,754
# of Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (b)	15,825
Subtract: # of groups to submit improvement activities on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (c)	80
Add in: # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (d)	16
# of Groups and Virtual Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (e)	15,761
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2020 MIPS performance period (CY 2020 Proposed Rule) (f) = (a) + (b) + (e)	118,515
* Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (CY 2019 Final Rule) (g)	136,004
Difference between CY 2020 Proposed Rule and CY 2019 Final Rule (h) = (g) − (f)	−17,489

* Currently approved by OMB under control number 0938–1314 (CMS–10621).

Consistent with the CY 2019 PFS final rule, we estimate that the per response time required per individual or group is 5 minutes at $90.02/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set

of authenticated credentials (83 FR 60016).

As shown in Table 93, we estimate an annual burden of 9,876 hours (118,515 responses × 5 minutes/60) at a cost of $889,060 (9,876.25 hr × $90.02/hr).

TABLE 93—ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a).	118,515.
Total Annual Hours Per Respondent (b)	5 minutes.
Total Annual Hours (c)	9,876.25.
Labor rate for a computer systems analyst to submit improvement activities (d)	$90.02/hr.
Total Annual Cost (e) = (a) * (d)	$889,060.

As shown in Table 94, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −1,457 hours (−17,489 responses × 5 minutes/60) at a cost of −$131,197 (−1,457 hr $90.02/hr).

TABLE 94—CHANGE IN ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	11,334
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	9,876
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−1,457
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,020,257
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$889,060
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$131,197

i. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of improvement activities. However, we have adjusted our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule, for the 2018 and future MIPS performance periods, stakeholders were provided an opportunity to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2018 Annual Call for Activities lasted from February 1, 2018 through March 1, 2018, during which we received 128 nominations of activities which were evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2019 Improvement Activities Inventory. Based on the number of improvement activity nominations received in the CY 2018 Annual Call for Activities, we estimate that we will receive 128 nominations for the 2020 Annual Call for Activities, which is an increase of 3 from the 125 nominations currently approved by OMB. The 2019 Annual Call for Activities ends on July 1, 2019; assuming updated information is available, we will update our estimate in the final rule.

We estimate 1.2 hours at $109.36/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $202.86/hr for a clinician's review. As shown in Table 95, we estimate an annual burden of 256 hours (128 nominations × 2 hr/nomination) at a cost of $37,571 (128 × [(1.2 hr × $109.36/hr) + (0.8 hr × $202.86/hr)]).

TABLE 95—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
# of Nominations of New Improvement Activities (a)	128
# of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
# of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d) = (b) + (c)	2
Total Annual Hours (e) = (a) * (d)	256
Cost to Identify and Submit Activity (@practice administrator's labor rate of $109.36/hr) (f)	$131.23
Cost to Identify Improvement Activity (@physician's labor rate of $202.86/hr) (g)	$162.29

TABLE 95—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES—Continued

	Burden estimate
Total Annual Cost Per Respondent (h) = (f) + (g)	$293.52
Total Annual Cost (i) = (a) * (h)	$37,571

As shown in Table 96, using our unchanged currently approved per respondent burden estimate, the increase in the number of nominations results in an adjustment of 6 hours at a cost of $881 {3 activities × [(1.2 hr × $109.36/hr) + (0.8 hr × $202.86/hr)]}.

TABLE 96—CHANGE IN ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	250
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	256
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	6
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$36,690
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$37,571
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$881

j. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy, including for the 10 episode-based measures we are proposing to include in the cost performance category as discussed in section III.K.3.c.(2)(b)(iii) of this rule. Moreover, the provisions of this proposed rule do not result in the need to add or revise or delete any claims data fields. Therefore, we are not proposing any new or revised collection of information requirements or burden for MIPS eligible clinicians resulting from the cost performance category.

k. Quality Payment Program ICRs Regarding Partial QP Elections (§§ 414.1310(b)(ii) and 414.1430)

This rule does not propose any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we propose to adjust our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section III.K.4.d.(2)(b), we propose that, beginning for eligible clinicians who become Partial QPs in the 2020 MIPS performance period, Partial QP status will only apply to the TIN/NPI combination through which Partial QP status is attained. Any Partial QP election will only apply to TIN/NPI combination through which Partial QP status is attained so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still report under MIPS for other TIN/NPI combinations. This proposal will potentially increase the total number of Partial QP elections to participate in MIPS if clinicians achieve Partial QP status under multiple TIN/NPI combinations.

As shown in Table 97, based on our predictive QP analysis for the 2020 QP performance period, which accounts for the increase in QP and Partial QP thresholds, we estimate that 12 APM Entities and 2,010 eligible clinicians will make the election to participate as a Partial QP in MIPS representing approximately 15,500 Partial QPs, an increase of 1,941 from the 81 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate an annual burden of 505.5 hours (2,022 respondents × .25 hr/election) at a cost of $45,080 (505.5 hours × $90.02/hr).

TABLE 97—ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
# of respondents making Partial QP election (6 APM Entities, 75 eligible clinicians) (a)	2,022
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a) * (b)	505.5
Labor rate for computer systems analyst (d)	$90.02/hr
Total Annual Cost (d) = (c) * (d)	$45,505

As shown in Table 98, using our unchanged currently approved per respondent burden estimate, the increase in the number of Partial QP elections results in an adjustment of 485.25 (1,941 elections × 0.25hr) at a cost of $43,682 (485.25 hr × $90.02/hr).

TABLE 98—CHANGE IN ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	20.25
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	505.5
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	485.25
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$1,823
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$45,505
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$43,682

l. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1440) and Eligible Clinician Initiated Process (§ 414.1445)

As indicated below, the proposed requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1440)

This rule does not propose any new or revised collection of information requirements related to the Payer-Initiated Process. However, we propose to adjust our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. As mentioned above, the adjusted burden will be submitted to OMB for approval.

As shown in Table 99, based on the actual number of requests received in the 2018 QP performance period, we estimate that in CY 2020 for the 2021 QP performance period 110 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 50 remaining other payers), a decrease of 105 from the 215 total requests currently approved by OMB under the aforementioned control number. We estimate it will take 10 hours at $90.02/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 1,100 hours (110 submissions × 10 hr/submission) at a cost of $99,022 (1,100 hr × $90.02/hr).

TABLE 99—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
# of other payer payment arrangements (15 Medicaid, 100 Medicare Advantage Organizations, 100 remaining other payers) (a)	110
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	1,100
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	$99,022

As shown in Table 100, using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 215 to 110 results in an adjustment of −1,050 hours (−105 requests × 10 hr) at a cost of −$94,521 (−1,050 hr × $90.02/hr).

TABLE 100—CHANGE IN ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	2,150
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	1,100
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−1,050
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$193,543
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$99,022
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$94,521

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule does not propose any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes to under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule does not propose any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. However, we propose to adjust our currently approved burden estimates based on updated projections for the 2020 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we will not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we will need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule also noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two finalized snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In the CY 2019 PFS final rule, we finalized the addition of a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single (the same) APM Entity (83 FR 59936). This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) Attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31.

As shown in Table 101, we assume that 20 APM Entities, 448 TINs, and 83 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019, and increase of 242 from the 309 total submissions currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $109.36/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 2,755 hours (551 respondents × 5 hr) at a cost of $301,287 (2,755 hr × $109.36/hr).

TABLE 101—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
# of APM Entities submitting data for All-Payer QP Determinations (a)	20
# of TINs submitting data for All-Payer QP Determinations (b)	448
# of eligible submitting data for All-Payer QP Determinations (c)	83
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a) *(d)] + [(b) * (d)] + [(c) * (d)]	2,755

TABLE 101—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS—Continued

	Burden estimate
Labor rate for a Practice Administrator (h)	$109.36/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g) * (h)	$301,287

As shown in Table 102, using our unchanged currently approved per respondent burden estimate, the increase in the number of data submissions from 309 to 551 results in an adjustment of 1,210 hours (242 requests × 5 hr) at a cost of $132,326 (1,210 hr × $109.36/hr).

TABLE 102—CHANGE IN ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	1,545
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	2,755
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	1,210
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$168,961
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$301,287
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	$132,326

m. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule does not propose any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we propose to adjust our currently approved burden estimates based on data from the 2018 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). Subject to renewal, the control number is currently set to expire on January 31, 2022. It was last approved on January 29, 2019, and remains active.

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 11,516 (0.10 × 115,163 voluntary MIPS participants) clinicians and groups, a decrease of 101 from the currently approved estimate of 11,617. This decrease is due to the availability of updated estimates of QPs and APM participation for the 2020 performance period. Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the Regulatory Impact Analysis section of the CY 2019 PFS final rule, we estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

In section III.K.3.h.(6) of this rule, we propose to publicly report (1) an indicator if a MIPS eligible clinician is scored using facility-based measurement beginning with Year 3 (2019 performance information available for public reporting in late 2020) and (2) aggregate MIPS data beginning with Year 2 (2018 performance information available for public reporting in late 2019). We believe it is possible that the percentage of voluntary participants electing not to participate in public reporting may change as a result of this proposals, we lack the ability to predict the behavior of clinicians' response to this proposal. Table 103 shows that for these voluntary participants, we estimate it will take 0.25 hours at $90.02/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,879 hours (11,516 requests × 0.25 hr/request) at a cost of $259,168 (2,879 hr × $90.02/hr).

TABLE 103—ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	11,516
Total Annual Hours per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a) * (b)	2,879
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for Opt-out Requests (e) = (a) * (d)	$259,168

As shown in Table 104, using our unchanged currently approved per respondent burden estimate, the decrease in the number of opt outs by voluntary participants from 11,617 to 11,516 results in an adjustment of 25.25 hours (101 requests × 0.25 hr) at a cost of −$2,273 (25.25 hr × $90.02/hr).

TABLE 104—CHANGE IN ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
Total Annual Hours for Respondents in CY 2019 Final Rule (a)	2,904.25
Total Annual Hours for Respondents in CY 2020 Proposed Rule (b)	2,879.00
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (c) = (b) − (a)	−25.25
Total Annual Cost for Respondents in CY 2019 Final Rule (d)	$261,441
Total Annual Cost for Respondents in CY 2020 Proposed Rule (e)	$259,168
Difference Between CY 2020 Proposed Rule and CY 2019 Final Rule (f) = (e) − (d)	−$2,273

n. Summary of Annual Quality Payment Program Burden Estimates

Table 105 summarizes this proposed rule's burden estimates for the Quality Payment Program. To understand the burden implications of the policies proposed in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2019 PFS final rule into the 2020 MIPS performance period. Our estimated baseline burden estimates reflect the availability of more accurate data to account for all potential respondents and submissions across all the performance categories, more accurately reflect the exclusion of QPs from all MIPS performance categories, and better estimate the number of third-parties likely to self-nominate as qualified registries and QCDRs, as well as the number of measures submitted per QCDR. The baseline burden estimate is 3,312,523 hours at a cost of $315,630,967. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2019 PFS final rule due to updated data and assumptions. The difference of 1,619 hours and $147,173 between this baseline estimate and the total burden shown in Tables 105 and 107 is the burden associated with the proposals to require QCDRs to submit measure testing data to require proposed quality measures and QCDR measures to be linked to existing cost measures, improvement activities, and MIPS Value Pathways, if possible at the time of self-nomination and to describe the quality improvements services they intend to support.

TABLE 105: Summary of Proposed Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Responses *	Proposed Responses	Change in Responses	Currently Approved Total Burden Hours*	Proposed Total Burden Hours	Change in Total Burden Hours
§ 414.1400 Registry self- nomination	150	290	140	450	870	420
§ 414.1400 QCDR self-nomination	200	91	-109	2,400	2912	512
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type	257,260	109,951	-147,309	3,653,092	1,561,304	-2,091,788
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type	81,981	116,591	34,610	744,633	1,058,996	314,363
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	51,861	51,787	-74	414,888	414,296	-592
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface	286	104	-182	17,637.7	6,413.7	-11,224
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	67	51	-16	16.75	12.75	-4
(Quality Performance Category) Call for Quality Measures	140	26	-114	630	143	-487
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	6,041	6,025	-16	1,510	1,506	-4
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission	93,869	93,863	-6	250,317	250,301	-16
(Promoting Interoperability Performance Category) Call for Promoting Interoperability Measures	47	28	-19	23.5	14	-9.5
§ 414.1360 (Improvement Activities Performance Category) Data Submission	136,004	118,515	-17,489	11,334	9,876	-1,457
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	125	128	3	250	256	6
§ 414.1430 Partial Qualifying APM Participant (QP) Election	81	2,024	1,943	20.25	506	485.75
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	215	110	-105	2,150	1,100	-1,050
§ 414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	309	551	242	1,545	2,755	1,210
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants	11,617	11,516	-101	2,904.25	2,879	-25.25
TOTAL	**640,253**	**511,651**	**-128,602**	**5,103,801**	**3,314,118**	**-1,789,683**

*Currently approved under OMB control number 0938-1314 (CMS-10621).

Table 106 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this proposed rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 3 policies that reflect updated data and revised methods.

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TABLE 106: Reasons for Change in Burden Compared to the Currently Approved CY 2019 Information Collection Burdens

QPP Table	Changes in burden due to CY 2020 Proposed Rule policies	Adjustments in burden from continued CY 2019 Final Rule policies due to revised methods or updated data
Table 65: Qualified Registry Self-Nomination	None.	Increase in number of respondents due to availability of data indicating number of existing QCDRs which would not meet previously finalized QCDR requirements effective beginning in 2020 performance period.
Table 67: QCDR Self-Nomination	*Increase of 11.5 hours (1 hour per proposed measure) per QCDR self-nomination due to proposed policy to require QCDRs to provide a linkage between proposed QCDR measures and related cost measures, improvement activities, and MIPS Value Pathways.* *Increase of 5.75 hours (0.5 hour per proposed measure) per QCDR nomination due to proposed policy to require QCDRs to provide measure testing data at the time of self-nomination* *Increase of 0.25 hour per QCDR to describe the quality improvements services they intend to support as part of their self-nomination.*	Decrease in number of respondents due to availability of data indicating number of existing QCDRs which would not meet previously finalized QCDR requirements effective beginning in 2020 performance period. Increase in burden per respondent due to revised estimate of average number of measures per QCDR for which information is submitted.
Table 73: Quality Performance Category Medicare Part B Claims Collection Type	None.	Decrease in number of respondents due to use of updated data incorporating limitation on submission of quality data via Medicare Part B claims to small practices. Decrease in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 75: Quality Performance Category QCDR/ MIPS CQM Collection Type	None.	Increase in number of respondents due to use of updated data incorporating limitation on submission of quality data via Medicare Part B claims to small practices. and our assumption that affected clinicians will submit via the MIPS CQM collection type. Net decrease in total number of respondents (number of individual submitters decreased while the number of group submitters increased) due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 77: Quality Performance Category eCQM Collection Type	None.	Net decrease in total number of respondents (number of individual submitters decreased while the number of group submitters increased) due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.

QPP Table	Changes in burden due to CY 2020 Proposed Rule policies	Adjustments in burden from continued CY 2019 Final Rule policies due to revised methods or updated data
Table 79: Quality Performance Category CMS Web Interface	None.	Decrease in number of respondents due to updated data from the 2018 MIPS performance period.
Table 81: Registration for CMS Web Interface	None.	Decrease in number of respondents due to updated data from the 2018 registration period.
Table 83: Call for Quality Measures	*Increase of 1 hour per measure due to proposed requirement to link nominated measures to existing cost measures or improvement activities.*	Decrease in number of measures submitted due to updated data.
Table 86: Reweighting Applications for Promoting Interoperability and Other Performance Categories	None.	Decrease in number of applications submitted due to updated data.
Table 88: Promoting Interoperability Performance Category Data Submission	None.	Increase in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 90: Call for Promoting Interoperability Measures	None.	Decrease in number of measures submitted due to updated data.
Table 93: Improvement Activities Submission	None.	Decrease in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 95: Nomination of Improvement Activities	None.	Increase in number of activities nominated due to updated data.
Table 97: Partial QP Election	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 99: Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 101: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 103: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to updated projections for the number of voluntary participants in the 2020 MIPS performance period.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 107: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number**	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
§§ 403.902 and 403.904 ("Nature of Payment" Categories)***	0938-1237	400	400	5 - 30	5,895	44.92	264,804
		1,600	1,600	2 - 5	7,767	varies	410,941
§§ 403.902 and 403.904 (Standardizing Data Reporting for Covered Drugs, Devices, Biologicals, or Medical Supplies)***	0938-1237	450	450	20 - 100	24,840	44.92	1,115,813
		850	850	10 – 40	21,100	varies	1,013,740
		750	750	2 - 10	5,637	varies	311,384
Medicare Enrollment of Opioid Treatment Programs	0938-0685	633	633	2	1,900	37.50	262,523
Provider Agreement as Part of Enrollment Process	0938-0832-	633	633	0.167	53	varies	12,501
Quality Payment Program (See Subtotal Under Table 105)	0938-1314	379,749	-128,635	varies	-1,789,733	varies	-170,169,740
TOTAL		384,432	-123,919	Varies	-1,722,544	Varies	-166,778,034

* As it relates to the PRA, this rule will not impose any non-labor costs.

**OMB and CMS' PRA package ID numbers: OMB 0938-1237 (CMS-10495), OMB 0938-0685 (CMS-855B), and OMB 0938-1314 (CMS-10621).

***The burden for these changes to the Open Payments program represent one-time system changes.

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D. Submission of Comments

We have submitted a copy of this rule to OMB for its review of the rule's proposed information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on the proposed information collection requirements and burden. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1715–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and sections 2005 6063, and 6111 of the SUPPORT for Patients and Communities Act of 2018. This proposed rule also makes changes to payment policy and other related policies for Medicare Part B.

This proposed rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed regulatory impact analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this proposed rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other

providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, *see* the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and non-physician practitioners in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule, if finalized, is considered an E.O. 13771 regulatory action. We estimate the rule generates $3.46 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we are proposing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2019 with payment rates for CY 2020 using CY 2018 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for CY 2015 and beyond. The update adjustment factor for CY 2020, as required by section 53106 of the Bipartisan Budget Act of 2018, is 0.00 percent before applying other adjustments.

To calculate the proposed CY 2020 CF, we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimated the CY 2020 PFS CF to be 36.0896 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.00 percent update adjustment factor specified under

section 1848(d)(18) of the Act. We estimate the CY 2020 anesthesia CF to be 22.2774, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 108—CALCULATION OF THE PROPOSED CY 2020 PFS CONVERSION FACTOR

CY 2019 Conversion Factor		36.0391
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Conversion Factor		36.0896

TABLE 109—CALCULATION OF THE PROPOSED CY 2020 ANESTHESIA CONVERSION FACTOR

CY 2019 National Average Anesthesia Conversion Factor		22.2730
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment.	−0.12 percent (0.9988)	
CY 2020 Conversion Factor		22.2774

Table 110 shows the payment impact on PFS services of the policies contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 110 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 110.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2018 utilization and CY 2019 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2020 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2020 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 110: CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	0%	0%	0%	0%
Anesthesiology	$1,993	0%	0%	0%	0%
Audiologist	$70	0%	0%	0%	1%
Cardiac Surgery	$279	-1%	-1%	0%	-1%
Cardiology	$6,595	0%	0%	0%	0%
Chiropractor	$750	0%	0%	-1%	-1%
Clinical Psychologist	$787	1%	2%	0%	3%
Clinical Social Worker	$781	0%	3%	0%	3%
Colon And Rectal Surgery	$162	0%	1%	0%	1%
Critical Care	$346	0%	0%	0%	1%
Dermatology	$3,541	0%	1%	-1%	0%
Diagnostic Testing Facility	$697	0%	-2%	0%	-2%
Emergency Medicine	$3,021	1%	0%	1%	1%
Endocrinology	$488	0%	0%	0%	0%
Family Practice	$6,019	0%	0%	0%	0%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	0%	0%	0%	0%
General Surgery	$2,031	0%	0%	0%	0%
Geriatrics	$187	0%	0%	0%	0%
Hand Surgery	$226	0%	0%	0%	1%
Hematology/Oncology	$1,673	0%	0%	0%	0%
Independent Laboratory	$592	0%	1%	0%	1%
Infectious Disease	$640	0%	0%	0%	0%
Internal Medicine	$10,507	0%	0%	0%	0%
Interventional Pain Mgmt	$885	0%	0%	0%	1%
Interventional Radiology	$432	0%	-2%	0%	-2%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	0%	0%	0%	1%
Neurology	$1,503	-1%	3%	0%	2%
Neurosurgery	$802	0%	0%	-1%	-1%
Nuclear Medicine	$50	0%	1%	0%	1%
Nurse Anes / Anes Asst	$1,291	0%	0%	0%	0%
Nurse Practitioner	$4,503	0%	0%	0%	0%
Obstetrics/Gynecology	$620	0%	1%	0%	1%
Ophthalmology	$5,398	-2%	-3%	0%	-4%
Optometry	$1,325	0%	-1%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-2%
Orthopedic Surgery	$3,734	0%	0%	0%	1%
Other	$34	0%	0%	0%	1%
Otolarngology	$1,225	0%	0%	0%	0%
Pathology	$1,203	0%	0%	0%	0%
Pediatrics	$62	0%	0%	0%	0%
Physical Medicine	$1,110	0%	0%	0%	0%
Physical/Occupational Therapy	$4,248	0%	0%	0%	0%
Physician Assistant	$2,637	0%	0%	0%	0%
Plastic Surgery	$369	0%	0%	0%	0%
Podiatry	$1,998	0%	1%	0%	1%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Portable X-Ray Supplier	$94	0%	0%	0%	0%
Psychiatry	$1,120	0%	0%	0%	1%
Pulmonary Disease	$1,658	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,756	0%	0%	0%	0%
Radiology	$4,971	0%	0%	0%	-1%
Rheumatology	$534	0%	0%	0%	0%
Thoracic Surgery	$352	-1%	0%	0%	-1%
Urology	$1,739	0%	1%	0%	1%
Vascular Surgery	$1,203	0%	-2%	0%	-2%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

* Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2020 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical social workers, neurology, emergency medicine, and podiatry reflect increases relative to other physician specialties. These increases can largely be attributed to finalized increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the continuing implementation of the adjustment to indirect PE allocation for some office-based services.

The estimated impacts for several specialties, including ophthalmology and optometry, reflect decreases in payments relative to payment to other physician specialties as a result of revaluation of individual procedures reviewed by the AMA's relative value scale update committee (RUC) and CMS. The estimated impacts for other specialties, including vascular surgery, reflect decreased payments as a result of continuing implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased-in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 1 percent increase for CY 2020 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 110), including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 110 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 110 displays the estimated CY 2020 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2020 PFS proposed rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts Related to Proposed Changes for Office/Outpatient E/M Services for CY 2021

Although we are not proposing changes to E/M coding and payment for CY 2020, we are proposing certain changes for CY 2021. We provide the following impact estimate only for illustrative purposes. We believe these estimates provide insight into the magnitude of potential changes for certain physician specialties. Table 111 illustrates the estimated specialty level impacts associated with implementing the RUC-recommended work values for the office/outpatient E/M codes, as well as the revalued HCPCS add-on G-codes for primary care and certain types of specialty visits in 2020, rather than delaying until CY 2021.

TABLE 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented for CY 2021

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Allergy/Immunology	$236	4%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-7%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-8%
Cardiology	$6,595	2%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-7%	0%	0%	-7%
Clinical Social Worker	$781	-7%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	-1%	-1%	-4%
Critical Care	$346	-5%	-1%	0%	-6%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	-1%	-4%	0%	-4%
Emergency Medicine	$3,021	-6%	-2%	1%	-7%
Endocrinology	$488	11%	5%	1%	16%
Family Practice	$6,019	8%	4%	1%	12%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	8%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	2%	1%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	8%	4%	1%	12%
Independent Laboratory	$592	-3%	-1%	0%	-4%
Infectious Disease	$640	-3%	-1%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-3%	-3%	0%	-6%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-4%	0%	0%	-5%
Nurse Anes / Anes Asst	$1,291	-7%	-2%	0%	-9%
Nurse Practitioner	$4,503	5%	3%	0%	8%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-10%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-4%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolarngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-5%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	6%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-3%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-3%	-1%	-1%	-5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact*
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-5%	-3%	0%	-8%
Rheumatology	$534	9%	5%	1%	15%
Thoracic Surgery	$352	-5%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-5%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

** Column F May Not Equal The Sum Of Columns C, D, And E Due To Rounding.*

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Overall, those specialties that bill higher level established patient visits, such as endocrinology or family practice, see the greatest increases as those codes were revalued higher relative to the rest of the office/outpatient E/M code set. Those specialties that see the greatest decreases are those that do not generally bill office/outpatient E/M visits. Other specialty level impacts are primarily driven by the extent to which those specialties bill using the office/outpatient E/M code set and the relative increases to the particular office/outpatient E/M codes predominantly billed by those specialties. We note that any potential coding changes and recommendations in overall valuation for new and existing codes between the CY 2020 proposed rule and the CY 2021 final rule could impact the actual change in overall RVUs for office/outpatient visits relative to the rest of the PFS. Given the various factors that will be considered by the variety of stakeholders involved in the CPT and RUC processes, we do not believe we can estimate with any degree of certainty what the impact of potential changes might be. We also, note, however, that any changes in coding and payment for these services would be subject to notice and comment rulemaking.

As discussed elsewhere in this section of the proposed rule, we estimate this approach would lead to burden reduction for practitioners, while allowing a year of preparatory time and time for potential refinement over the next year as we take into account any feedback from stakeholders on these proposed changes.

D. Effect of Proposed Changes Related to Telehealth

As discussed in section II.F. of this proposed rule, we are proposing to add three new codes, HCPCS codes GYYY1, GYYY2, and GYYY3, to the list of Medicare telehealth services for CY 2020. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. The restrictions placed on Medicare telehealth by the statute limit the magnitude of utilization; however, we believe there is value in allowing physicians and patients the greatest flexibility when appropriate.

E. Other Provisions of the Proposed Regulation

1. Effect of Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section II.G of this proposed rule, Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act establishes a new Medicare Part B benefit for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) for episodes of care beginning on or after January 1, 2020. The Substance Abuse and Mental Health Services Administration (SAMHSA) currently performs regulatory certification of OTPs. Currently, SAMHSA certifies about 1,700 OTPs. They are located predominately in urban areas, tend to be free-standing facilities, and provide a range of services, including medication-assisted treatment (MAT). The payor mix for OTPs currently includes Medicaid, private payors, TRICARE, as well as individual pay patients. The total estimated Part B net impact, including FFS and Medicare Advantage, over 10 years is $1,024,000,000. In developing this estimate, it was assumed that the average treatment length would be 12 months in duration and the average rate per week in CY 2020 was assumed to be $148, which is a weighted average of the rates we are proposing for the bundled payments for treatment with methadone, buprenorphine, and naltrexone. These rates were assumed to be updated annually by the Medicare Economic Index (MEI). We assumed that the impact in the first year would be reduced by 50 percent due to potential delays in provider certification and system modifications. Additionally, any change to fee-for-service benefits has an associated impact on payments to Medicare Advantage plans so an adjustment was made to reflect this, based on the projected distribution of spending in each year. The estimate also accounts for the impact on the program due to the change in the Part B premium as a result of this provision. The Part B enrollment and MEI assumptions were based on the President's Fiscal Year 2020 Budget baseline that was released in March of 2019. As with all estimates, and particularly those for new separately billable services, this outcome is highly uncertain because the available information on which to base estimates is limited and is not directly

applicable to a new Medicare payment. The cost and utilization estimates are based on Medicare and Medicaid claims data for beneficiaries with OUD, together with statistics about the types of services typically furnished at OTPs.

It is difficult for us to predict how coverage of OTPs will specifically affect the market. We anticipate current OTPs may expand access to care for Medicare beneficiaries since they will be able to receive payment from Medicare for services furnished to beneficiaries when they previously were unable to do so. Coverage may also create financial incentives to establish new OTPs. However, since TRICARE, Medicaid, and some private payers already pay for OTP services, it is less clear whether the presence of Medicare payment rates will have any effect on current rates for OTP services or on new rates should additional private coverage be established.

2. Changes to the Ambulance Physician Certification Statement Requirement

This proposed rule would clarify the requirements at §§ 410.40 and 410.41 regarding the requirements for physician certification and non-physician certification statements and expand the list of staff members who can sign non-physician certification statements. While we believe that clarification of the regulatory provisions associated with physician certification and non-physician certification statements is needed and would be well received by stakeholders, we do not believe that these clarifications would have any substantive monetary or impact the amount of time needed to complete the certification statements. We believe the primary benefit of the clarification would be for providers and suppliers in preparing and submitting the original certification statements. It is feasible the clarification could result in fewer claims being denied. However, hypothetically, these denials are likely a small subset of the ambulance claim denials and those denied for technical PCS issues are likely appealed and overturned.

Moreover, we have examined the impact of expanding the list of individuals who may sign the non-physician certification statement. This added flexibility in accessing additional individuals to sign a non-physician certification statement would be needed only when the physician was unavailable. Thus, while we anticipate that some providers would use the increased flexibility, the precise impact is not calculable.

3. Medicare Ground Ambulance Services Data Collection System

As discussed in section III.B.2. of this proposed rule, section 50203(b) of the BBA of 2018 added a new paragraph (17) to section 1834(l) of the Act, which requires the Secretary to develop a data collection system to collect cost, revenue, utilization, and other information determined appropriate with respect to providers and suppliers of ground ambulance services. In section III.B.4 through III.B.7. of this proposed rule, we describe our proposals that would implement this section, including the data that would be collected through the data collection system, sampling methodology, requirements for reporting data, payment reductions that would apply to ground ambulance providers and suppliers that fail to sufficiently report data and that do not qualify for a hardship exemption, informal review process that would be available to ground ambulance providers and suppliers that are subject to a payment reduction, and our policies for making the data available to the public.

We estimate that ground ambulance providers and suppliers would need to engage in two primary activities with respect to these proposals, both of which would require them to incur cost and burden: Data collection and data reporting. The data collection activity includes: (1) Reviewing instructions to understand the data required for reporting; (2) accessing existing data systems and reports to obtain the required information; (3) obtaining required information from other entities where appropriate; and (4) if necessary, developing processes and systems to collect data that are not currently collected, but that they would be required to report under the data collection system. The data reporting activity includes entering the collected information in CMS's proposed web-based data collection system.

To estimate the data collection impact, we assumed that each ground ambulance organization that is selected to submit data for a year would take up to 20 hours to collect the required data, which would include 4 hours to review the instructions and 16 hours to collect the required data. These estimates were informed by our discussions with ambulance organizations during stakeholder engagements and through more in-depth interviews with nine ambulance organizations for the purpose of soliciting feedback on data collection instrument items as described in section III.B.3. and III.B.4. of this proposed rule. Most participants indicated that they would be able to provide some of the required information with an investment of 1–2 hours and complete information with additional hours to collect the missing data. Many participants indicated that they would need to reach out to other staff at the organization, at contracted organizations (such as billing companies), or at other entities (such as municipal government financial staff for government ambulance organizations) to collect required information that was not in the organization's accounting or billing systems. Some participants indicated that their organization would need to adjust data collection processes or collect new data over the course of a year to ensure that required data was available in the appropriate format prior to submission.

Actual data collection and reporting will vary depending on the mix of employees at sampled ambulance organizations, the staff with available time to dedicate to data collection and data reporting activities at each organization, the staff in different roles that already perform similar activities in each organization, and whether billing services are contracted out or conducted internally.

Because we expect that the staff (by category) that will contribute to data collection and reporting will be highly variable across ground ambulance organizations, we calculated a blended mean wage for the purposes of estimating burden. Table 112 lists the Standard Occupational Classification (SOC) categories contributing to the blended wage, the mean wage for each SOC specific to North American Industry Classification System (NAICS) industry code 621910 (Ambulance Services), and the relative contribution of each SOC to the blended mean. The source mean wage and employment data is from the Bureau of Labor Statistics May 2018 Occupational Employment Statistics data (available from *https://download.bls.gov/pub/time.series/oe/*) for the indicated SOC and NAICS codes, which was most recently available wage and employment data set. We assumed that financial clerks (SOC category 433000) would account for 25 percent of the total data collection and reporting effort, and that six other SOC categories would contribute to the remaining 75 percent (*see* Table 112).

TABLE 112—ESTIMATED MEAN HOURLY WAGES FOR OCCUPATIONS INVOLVED IN DATA COLLECTION

D–6	Mean hourly wage ($)	Weight (% effort) *
Top Executives (111000)	51.49	17
Other Management Occupations (119000)	39.23	12
Business and Financial Operations Occupations (130000)	28.60	15
Secretaries and Administrative Assistants (436010)	18.11	10
Other Office and Administrative Support Workers (439000)	16.20	10
Financial Clerks (433000)	18.51	25
First-Line Supervisors of Office and Administrative Support Workers (431011)	27.92	10
Blended Mean Hourly Wage	28.91	100

* **Note:** Weights may not sum to 100 percent due to rounding. Source: Bureau of Labor Statistics Occupational Employment Statistics, May 2018, available from *https://download.bls.gov/pub/time.series/oe/.*

In addition, we calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage. Although we recognize that fringe benefits and overhead costs may vary significantly by employer, and that there are different accepted methods for estimating these costs, doubling the mean blended wage rate to estimate total cost is an accepted method to provide a reasonably accurate estimate. Therefore, assuming a mean blended wage of $28.91 for data collection, and assuming the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, we calculated at a wage plus benefits estimate of $57.82 per hour of data collection. To calculate at the total data collection cost per sampled ground ambulance organization, we multiplied the time required for data collection by the burdened hourly wage (20 hours * $57.82/hour) for a total of $1,156.

We discussed several sampling options in section III.B.5. of this proposed rule. Our proposed sampling rate of 25 percent would yield an expected 2,690 respondents in the first sample, resulting in a total estimated data collection cost of $3,110,684 (2,690 respondents * $1,156 per respondent).

To estimate the cost of data reporting, we assumed it will require 3 hours to enter, review, and submit information into the proposed web-based data collection system. The estimate of 3 hours was also informed by interviews with nine ambulance organizations to solicit feedback on the data instrument items under consideration. We included time for staff to review the collected data before entering it into the data collection system. We also assumed that staff responsible for reporting the data would have the same blended hourly wage used to estimate data collection costs above ($28.91) as the staff that collected the data. Again, assuming the cost of overhead at 100 percent of the mean hourly wage, we calculated at a wage plus benefits estimate of $57.82. Therefore, we estimate a per-respondent cost for data submission of $173.46 (3 hours * $57.82/hour). To calculate the total cost for data reporting under a 25 percent sampling rate, we multiplied the number of ground ambulance organizations sampled annually by the time required for data entry times the total hourly wage estimate, for a total of $466,603 across all respondents (2,690 respondents * 3 hours * $57.82/hour).

Adding the total data collection and reporting costs yields a total annual impact for ground ambulance organizations of $3,577,287 ($3,110,684 for data collection [2,690 respondents * 20 hours * $57.82/hour] + $466,603 total cost for data submission [2,690 respondents * 3 hours * $57.82/hour]) with a 25 percent sampling rate. Our estimate of total annual impact would be lower at $1,430,649 ($1,244,042 for data collection [1,076 respondents * 20 hours * $57.82/hour] + $186,606 for data submission [1,076 respondents * 3 hours * $57.82/hour]) under a 10 percent sampling rate alternative and higher at $7,153,244 ($6,220,212 for data collection [5,379 respondents * 20 hours * $57.82/hour] + $933,032 for data submission [5,379 respondents * 3 hours * $57.82/hour]) under a 50 percent sampling rate. In all cases, the estimated cost of collecting and reporting data is $1,330 per organization sampled ($1,156 for data collection [20 hours * $57.82/hour] + $173.46 for data submission [3 hours * $57.82/hour]). The per-organization estimate reflects an average. Based on discussions with ambulance organizations to provide feedback on instrument items, we do not anticipate that larger or smaller ambulance organizations in terms of transport volume, costs, or revenue will face systematically more or less burden in data collection or reporting. While larger organizations generally have higher transport volumes, costs, and revenue, and more complex financial arrangements that may increase reporting burden, they also tend to have existing data collection and reporting processes and staff that will reduce the additional effort required to submit the required data. On the other hand, while smaller organizations have less data to collect and report, they may not have current processes in place to begin collecting some required data.

b. Hardship Exemption Process

As discussed in section III.B.7.b. of this proposed rule, we are proposing a process for ground ambulance organizations to request and for CMS to grant significant hardship exemptions from the 10 percent payment reduction. To request a significant hardship exemption, we are proposing that a ground ambulance organization would be required to complete and submit a request form that we would make available on the Ambulances Services Center website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.*

We estimate that 25 percent of the total number of ground ambulance organizations will be selected each year as the representative sample to report the required information under the data collection system. That is, 25 percent out of the total 10,758 NPIs, or 2,690 ambulance providers and suppliers.

While we expect that few, if any, ground ambulance organizations will request a hardship exception, we do not have experience in collecting data from ground ambulance organizations that could be used to develop an estimate, so we are basing our estimate on the total number of organizations being surveyed. As a result, we estimate that a total of 2,690 ground ambulance organizations would apply for a hardship exemption, and that it would take 15 minutes for each of these ground ambulance organizations 15 minutes to complete and submit the request form.

We assumed for purposes of this estimate that the mix of staff responsible for completing this form would have the same blended hourly wage used to estimate the data collection and data reporting costs. We also calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, as we did above. As a result, we estimated that the total cost burden associated with the completion and submission of the hardship exemption request form would be approximately $38,884.

c. Informal Review Process

As discussed in section III.B.7.c. of this proposed rule, we are proposing a process in which a ground ambulance organization may seek an informal review of our determination that it is subject to the 10 percent reduction.

We estimate that a collection of information burden of 15 minutes for a ground ambulance provider or supplier who is requesting an informal review to gather the requested information and send an email to our AMBULANCEODF mailbox.

Again, we are using the total number of ambulance organizations survey each year to develop our estimates. Therefore, a total of 40,350 minutes (15 × 2,690) or 672.5 hours for 2,690 ambulance providers and suppliers to complete this form. Taking into account the same blended mean hourly wage and fringe benefits as we did for our other estimates, we estimate that the total for all sampled ambulance providers and suppliers to submit the form would be approximately $38,884.

4. Intensive Cardiac Rehabilitation (ICR)

As discussed in section III.C. of this proposed rule, we are adding stable, chronic heart failure (CHF) (defined as patient with left ventricular ejection fraction of 35 percent or less and NYHA class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks) to the list of covered conditions for ICR, as well as, the ability for use to use the NCD process to add additional covered conditions for ICR. Heart failure impacts approximately 5.7 million adults,[141] and approximately 80 percent of individuals over age 65 have heart failure.[142] (The majority (86 percent) of Medicare beneficiaries are over age 65.[143]) We estimate 4,560,000 beneficiaries over age 65 have heart failure.

The uptake by beneficiaries has historically been low for CR and ICR. From February 2014 to 2017, after stable CHF was added to the covered conditions for CR, only 439,888 claims were processed for this service with a diagnosis code of CHF. Less than 1 percent of beneficiaries with heart failure utilized CR. Given that the uptake of ICR has been even lower than CR, we expect the same trend (low uptake) for intensive cardiac rehabilitation due to the nature of these programs which entail rehabilitation through lifestyle modification. We conducted a claims analysis that examined claims prior to and after a 2014 NDC that added stable CHF to the list of covered conditions for CR. Prior to the implementation of stable CHF as a covered condition for CR, 1.8 percent of claims for CR included a diagnosis code for CHF. After implementation, 4.7 percent of claims for CR included a diagnosis code for CHF. Therefore, for ICR, which has historically been utilized much less than CR (for example, when all CR and ICR claims are combined, only 1 percent of the claims are for ICR), we anticipate there may be a similar slight percentage increase in claims for ICR for treatment of stable CHF. Assuming a 4.7 percent increase in ICR claims due to adding stable CHF as a covered condition, we estimate an increase of 3,378 claims annually. For 2019, the facility and non-facility prices for CR and ICR are the same, and the average price is $120.93. Therefore, based on our estimated increase in claims, at an average price of $120.93, the estimated total cost of adding stable, chronic heart failure to the list of covered conditions for ICR is estimated at $408,502 annually. From 2010–2017, the median number of ICR visits per calendar year was 18 visits per beneficiary. Therefore, based on our expected increase in the number of claims (3,378), the estimated number of beneficiaries covered would be 187. Based on these estimates, we estimate there will only be a negligible impact on Medicare expenditures from this proposed change.

Additionally, we do not anticipate providers currently offering ICR would need to obtain any specialized technology and equipment to treat ICR patients with stable CHF beyond what they would obtain for ICR patients seeking treatment for the existing six covered conditions.

When this proposed rule is finalized, we will cover the seven cardiac conditions that constitute the vast majority of cardiac conditions that CR and ICR can treat. Due to the breadth of the proposed and existing covered conditions, we do not anticipate the need to use the NCD process to add additional covered conditions to CR and ICR in the near future.

Lastly, while CR and ICR have low utilization at this point in time, an increase in the number of CR and/or ICR providers in underserved areas could result in an increase in utilization due to increased availability/proximity to services. However, we are not able to accurately quantify the number of entities that would seek approval as CR or ICR programs. Additionally, we acknowledge, that the expansion of coverage to ICR could generate attention around the importance of CR/ICR and may increase beneficiary utilization.

5. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we propose to align the eCQMs available for Medicaid EPs in 2020 with those available for MIPS eligible clinicians for the CY 2020 performance period. We anticipate that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on those eCQMs for 2020. Not implementing this alignment could lead to increased burden because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program, if they opt to report on newly added eCQMs for MIPS. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2020 to maintain current eCQM lists and specifications. State expenditures to make any systems changes required as a result of this proposal would be eligible for 90 percent Federal financial participation.

For 2020, we propose to require that Medicaid EPs report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome

[141] Centers for Disease Control, Heart Failure Fact Sheet, *https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_failure.htm.*

[142] Vigen, Rebecca et al. ''Aging of the United States population: impact on heart failure.'' Current heart failure reports vol. 9,4 (2012): 369–74. doi:10.1007/s11897–012–0114–8.

[143] CMS, 2019 Fast Facts, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html.*

measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). If no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she could report on any six eCQMs that are relevant. This proposal would be a continuation of our policy for 2019 and we believe it would create no new burden for EPs or states.

We also propose that the 2020 eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program who have demonstrated meaningful use in a prior year would be a minimum of any continuous 274-day period within CY 2020. We are proposing to shorten the reporting period from a full calendar year to enable states to take attestations for 2020 as early as October 1, 2020. We believe this would improve states' flexibility as they move toward the end of the Medicaid Promoting Interoperability Program and the December 31, 2021 statutory deadline to make incentive payments. This should add no additional burden for EPs or CEHRT vendors, as Certified EHR Technology (CEHRT) should be able to run eCQM reports for any number of days and during any time period. The proposed eCQM reporting period would be a minimum and EPs could continue to report on a full calendar year if they wish. As in previous years, the 2020 eCQM reporting period for EPs attesting to meaningful use for the first time would be any continuous 90-day period within the calendar year.

Finally, we are proposing to change Medicaid policy for 2021 related to EP Meaningful Use Objective 1, Measure 1 (Conduct or review a security risk analysis (SRA)). We are proposing to allow Medicaid EPs to conduct an SRA at any time during CY 2021, even if the EP conducts the SRA after attesting to meaningful use of CEHRT to the state. A Medicaid EP who has not completed an SRA for CY 2021 by the time he or she attests to meaningful use of CEHRT for CY 2021 would be required to attest that he or she will complete the required SRA by December 31, 2021. Currently, this measure must be completed in the same calendar year as the EHR reporting period. This may occur before, during, or after the EHR reporting period, though if it occurs after the EHR reporting period it must occur before the provider attests to meaningful use of CEHRT or before the end of the calendar year, whichever comes first. In practice, this means that EPs do not attest to meaningful use of CEHRT before completing this measure. However, due to the changes we previously made to the EHR and eCQM reporting period timelines for CY 2021, all Medicaid EPs are expected to attest to meaningful use of CEHRT on or before October 31, 2021. Accordingly, if we did not propose to change the deadline for conducting the SRA, Medicaid EPs would no longer have the option of completing an SRA at the end of the calendar year, and would likely have to complete one well before December 2021. If an EP typically conducts the security risk analysis at the end of each year, this timeline could create burden for the EP, and may not be optimal for protecting information security, because it could disrupt the intervals between security risk analyses. We have also heard feedback from health care providers that SRAs are generally conducted for a whole clinic and the current requirement would create burden on non-EP health care providers in 2021. We believe our proposal would prevent additional burden for both EPs and non-EP health care providers.

This proposal could create burden for states, as they might have to adjust their pre-payment and post-payment verification plans and conduct more thorough audits for this meaningful use objective. However, states are already required to conduct adequate oversight of the Medicaid Promoting Interoperability Program, including routine tracking and verification of meaningful use attestations (*see* 42 CFR 495.318(b), 495.332(c), and 495.368), and we are not proposing to change that requirement for 2021. We have established at 42 CFR 495.322(b) that 90 percent Federal financial participation will be available for state administrative expenditures related to Medicaid Promoting Interoperability Program audits and appeals that are incurred on or before September 30, 2023.

6. Medicare Shared Savings Program

In section III.F.1.b. of this proposed rule, we summarize certain modifications to the quality measure set used to assess the quality performance of ACOs participating in the Shared Savings Program based on proposed changes made to the CMS Web Interface measures under the Quality Payment Program in section III.I.3.b.(1). Specifically, we are proposing: (1) The addition of one CMS Web Interface measure; (2) the removal of one CMS Web Interface Measure; (3) revisions to the numerator guidance for ACO–17—Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention; and (4) reverting ACO–43—Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91) to pay-for-reporting for 2 years to account for a substantive change in the measure.

The net result of these proposed modifications to the Shared Savings Program quality measure set would be a measure set of 23 measures. These proposed changes would have no impact on the number of measures an ACO is required to report; therefore, there is no expected change in reporting burden for ACOs.

7. Open Payments

a. Expanding the Definition of ''Covered Recipient'' (§§ 403.902, 403.904, and 403.908)

Our initial estimate based on the available information is that there will be approximately $10 million dollar per year in increased burden to reporting entities and the new covered recipient groups for submitting, collecting, retaining, and reviewing data. This estimate is based on existing burden calculations. It assumes that there will be 734,000 new records (~7 percent increase) reported about 205,000 (~33 percent increase) covered recipients.

We also believe there will be costs to reporting entities for updating their systems and reporting processes. However, we are unable to estimate these costs because they will vary depending on the reporting entity's individual circumstances.

As explained in section IV.5. of this proposed rule, section 6111(c) of the SUPPORT Act states that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the changes to the definition of a covered recipient. Therefore, a detailed breakdown is not provided in that section. The above estimates however, do provide a regulatory impact analysis of this provision.

b. Modification of the ''Nature of Payment'' Categories (§§ 403.902 and 403.904)

We anticipate minor additional costs for system updates associated with our proposed provision to modify the ''nature of payment'' categories. As we indicated in section III.F. of this proposed rule, said provisions are intended to add clarity. They will not increase the amount of information to be reported. Data already reported to us may simply be reported in a different category. We propose these changes

only to be made prospectively and do *not* propose to have manufactures and GPOs to make changes to previously reported data. This provision would, generally speaking, allow reporting entities to better characterize the nature of a payment and would not constitute a new requirement. Hence, the expected impact is minimal.

c. Standardizing Data Reporting (§§ 403.902 and 403.904)

Approximately 850 entities (approximately 53 percent), have reported a transaction that could require the addition of a device identifier if this proposed rule becomes final. The total cost of the addition of this new data element cannot be estimated because it would depend on: (1) Whether the entity already tracks this data element and (2) the extent to which the entity would need to update their system to be able to report this data element.

8. Medicare Enrollment of Opioid Treatment Programs

As stated previously in this proposed rule, we propose that OTP providers be required to not only enroll in Medicare, but also (1) pay an application fee at the time of enrollment and (2) submit a set of fingerprints for a national background check (via FBI Applicant Fingerprint Card FD–258) from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the OTP.

a. Application Fee

The application fees for each of the past 3 calendar years (CY) were or are $560 (CY 2017), $569, (CY 2018), and $586 (CY 2019). Consistent with § 424.518, the differing fee amounts were predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI–U) for the 12-month period ending on June 30 of the previous year. While we cannot predict future changes to the CPI, we note that the fee amounts between 2017 and 2019 increased by an average of $13 per year. We believe this is a reasonable barometer with which to establish estimates (strictly for purposes of this proposed rule) of the fee amounts in the first 3 CYs of this rule (that is, 2020, 2021, and 2022). We thus project a fee amount of $599 in 2020, $612 for 2021, and $625 for 2022.

Applying these prospective fee amounts to the number of projected applicants in the rule's first 3 years, we estimate a cost to enrollees of $1,058,433 (or 1,767 × $599) in the first year, $41,004 (or 67 × $612) in the second year, and $41,250 (or 66 × $625) in the third year.

b. Fingerprinting

Based on the experiences of the provider community to date, we estimate that it would take each owner (BLS: Top Executives) approximately 2 hours at $123.32/hr to obtain and submit the fingerprints. (According to the most recent BLS wage data for May 2018, the mean hourly wage for the general category of ''Top Executives'' is $61.66 (*see http://www.bls.gov/oes/current/oes_nat.htm#43-0000).* With fringe benefits and overhead, the figure is $123.32.)

As mentioned in the preamble of this proposed rule, SAMHSA statistics indicate that there are currently about 1,677 active OTPs; of these, approximately 1,585 have full certifications and 92 have provisional certifications.

Although we do not have specific data on the matter, we project, for purposes of our proposed burden estimates, a total of 1,500 such direct or indirect ownership interests in OTP providers that would require the submission of fingerprints over the first 3 years. This 1,500 figure is less than the 1,900 projected applicants (discussed in the ICR section of this rule) in the first 3 years following the final rule's publication because some applicants may have non-profit business structures and, thus, would not have owners. Furthermore, our estimation of individual owners who would qualify to submit fingerprints is based on a sampling of similar provider types, including DMEPOS suppliers (high risk), MDPP suppliers (high risk), rural health clinics (limited risk) and others.

Applying this figure to the aforementioned per year breakdown of applicants, we estimate a first year burden of 2,790 hours at a cost of $344,063 (2,790 hr × $123.32/hr). We obtained the 2,790 hour estimate by first dividing 1,767 (the number of first-year applicants) by 1,900, resulting in a figure of 0.93. We then multiplied 0.93 by 1,500 (the number of ownership interests over the 3-year period) and thereafter by 2 hours.

Applying this same formula, we project a second-year time estimate of 106 hours (or 0.0353 × 1,500 applicants × 2 hr) at a cost of $13,072 (106 hr × $123.32/hr), and a third-year estimate of 104 hours (or 0.0347 × 1,500 applicants × 2 hr) at a cost of $12,825 (104 hr × $123.32/hr). In aggregate, we estimate a burden of 3,000 hours (2,790 hr + 106 hr + 104 hr) at a cost of $369,960 ($344,063 + $13,072 + $12,825). When annualized over the 3-year period, we estimate an annual burden of 1,000 hours (3,000 hours/3) at a cost of $123,320 ($369,960/3).

9. Deferring to State Scope of Practice Requirements

a. Ambulatory Surgery Centers

As of May 2019 there were 5,767 Medicare-participating ASCs. We are proposing to revise § 416.42 to allow an anesthetist, or a physician, to perform the required examination before surgery for anesthesia risk and of the procedure to be performed. We proposed this revision to reduce ASC compliance burden and provide for patient assessment and care continuity while maintaining patient safety and care. At § 416.42(a)(1), we propose to allow an anesthetist, in addition to a physician, to perform the required pre-surgical risk and evaluation examination. This change would provide flexibility and allow either a physician or an anesthetist to perform the pre-surgical examination. In total, ASCs provided about 6.4 million services in 2016.[144] We assume that 30 percent of all procedures would utilize the services of a nurse anesthetist instead of a physician for this requirement, which would reduce the cost of the examination. We estimate the pre-surgical evaluation to take 15 minutes to complete. We are assuming these estimates based on previous experience and conversations with stakeholders. We acknowledge the uncertainty with these estimates and invite public comment on our assumptions to articulate the most accurate information in the final rule calculations. According to 2018 Bureau of Labor Statistics data, the hourly cost for a physician (including fringe benefits and overhead calculated at 100 percent of the mean hourly wage) is approximately $203 ($51 for 15 minute evaluation), and the hourly cost for a nurse anesthetist is approximately $168 ($42 for 15 minute evaluation). Assuming 1.92 million procedures annually, we can predict a savings of approximately $17.3 million (($51 − $42) × 1.92 million). We have used our best estimate as to the percentage of pre-surgical evaluations by anesthetists overall, however, we welcome any comments and evidence-based information that would inform our ability to provide the most accurate cost savings estimates.

b. Hospice

We are proposing to revise § 418.106 to permit hospices to accept orders for drugs from attending physicians who are physician assistants. We do not

[144] MEDPAC, Ambulatory surgical centers services 2017, p. 136.

believe that are any associated financial impacts for hospices.

10. Changes Due to Updates to the Quality Payment Program

In section III.K. of this proposed rule, we included our proposed policies for the Quality Payment Program. In this section of the proposed rule, we present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In MIPS, we estimate the total MIPS eligible population and the payment impacts by practice size for the 2020 MIPS performance period based on various proposed policies to modify the MIPS final score and the proposed new performance threshold and additional performance threshold.

Although the submission period for the second MIPS performance period ended in early 2019, the final data sets were not available in time to incorporate into the CY 2020 PFS proposed rule analysis. We intend to use data from the 2018 MIPS performance period for the final rule.

a. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. In addition, beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year would not need to report to MIPS and would not receive a MIPS payment adjustment to their Part B PFS payments. Eligible clinicians who do not become QPs, but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs will not receive the APM Incentive Payment. For the 2020 QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an APM Entity, or collectively furnish Part B covered professional services to at least 25 percent, but less than 35 percent, of their Medicare beneficiaries through an APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive, negative, or neutral. If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the fourth payment year (2022 payment year) of the Quality Payment Program in detail.

In section III.K.4.e.(3)(b)(ii) of this proposed rule, we propose to amend the marginal risk standard finalized in § 414.1420(d)(5) by amending paragraph (d)(5)(i) to provide that in event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in with exceptions for large losses and small losses as described in 414.1420(d). We do not yet have experience with QP and Partial QP Determinations under the All-Payer Combination Option as it will be operational for the first time this fall. To date, we have only determined a modest number of payment arrangements from non-Medicare payers that meet the Other Payer Advanced APM criteria. However, we expect this added flexibility in the marketplace may increase the number of arrangements in this category. Based on our analysis there are 12,000 providers within 5 percent of performance year 2020 QP thresholds in Advanced APMs, and therefore, could potentially benefit from participation in Other Payer Advanced APMs. Assuming a static marketplace, there are between 50–100 eligible clinicians that would benefit from the change in the marginal risk requirement at this time (that is, in 2020 QP performance period). This is because there are likely to be only a small number of eligible clinicians who both (1) participate in the models we determined were not Other Payer Advanced APMs, but would become Other Payer Advanced APMs under the proposed policy, and (2) have QP scores just below the QP threshold. While this number may grow in the future as payers adopt payment arrangements designed to reflect the change in the marginal risk requirement, we anticipate the incremental impact of this proposal will have a small impact on the number of clinicians that meet the QP threshold and the total number of payment arrangements that are determined to be Other Payer Advanced APMs.

Overall, we estimated that between 175,000 and 225,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year. These allowable charges for QPs are estimated to be between approximately $9,000 million and $12,000 million in total for the 2020 performance year. The analysis for this proposed rule used the APM Participation Lists for the Predictive QP determination file for 2019. We estimate that the total lump sum APM Incentive Payments will be approximately $500–600 million for the 2022 Quality Payment Program payment year.

In section VI.E.10., we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2020 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2020 QP

Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs for the 2020 QP Performance Period:

- Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model;
- Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative);
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Oncology Care Model (Two-Sided Risk Arrangements);
- Medicare ACO Track 1+ Model;
- Bundled Payments for Care Improvement Advanced;
- Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program);
- Primary Care First; and
- Medicare Shared Savings Program (Track 2, Basic Track Level E, and the ENHANCED Track).

We used the APM Participant Lists and Affiliated Practitioner Lists, as applicable, (*see* 81 FR 77444 through 77445 for information on the APM participant lists and QP determinations) for the Predictive QP determination file for 2019 to estimate QPs, total Part B allowed charges for covered professional services, and the aggregate total of APM incentive payments for the 2020 QP Performance Period. We examine the extent to which Advanced APM participants would meet the QP Thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

b. Estimated Number of Clinicians Eligible for MIPS Eligibility

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the 2020 MIPS performance period in this proposed rule, our scoring model used the first determination period from the 2018 MIPS performance period eligibility file as described in the CY 2018 Quality Payment Program final rule (82 FR 53587 through 53592). The first determination period from the 2018 MIPS performance period eligibility file was selected to maximize the overlap with the performance period data used in the model. In addition, since the low-volume threshold was finalized in the CY 2019 PFS final rule (83 FR 60075) to be based on covered professional services (services for which payment is made under, or is based on, the PFS and that are furnished by an eligible clinician), this eligibility file provided the information to base the low-volume threshold on covered professional services rather than all items and services under Part B. We included 1.5 million clinicians (*see* Table 113) who had PFS claims from September 1, 2016 to August 31, 2017 and included a 30-day claim run-out. We excluded from our analysis individual clinicians who were affected by the automatic extreme and uncontrollable policy finalized for the 2017 MIPS performance period/2019 MIPS payment year in the CY 2019 PFS final rule (83 FR 59876) as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group. Therefore, we excluded these clinicians when calculating those clinicians eligible for MIPS. We also excluded clinicians participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration for whom the waivers of MIPS reporting requirements and the associated payment consequences are applicable, as finalized in the CY 2019 PFS final rule (83 FR 59890).

For the estimated MIPS eligible population for the 2022 MIPS payment year, we restricted our analysis to clinicians who are a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); a physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional as finalized in the CY 2019 PFS final rule (83 FR 60076).

As noted previously, we excluded QPs from our scoring model since these clinicians are not MIPS eligible clinicians. To determine which QPs should be excluded, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019, using all available data because these data were available by TIN and NPI, could be merged into our model and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all Partial QPs would elect to participate in MIPS and included them in our scoring model and eligibility counts. The projected number of QPs excluded from our model is 124,413 for the 2019 QP performance period due to the expected growth in APM participation. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2020 Medicare QP Performance Period; hence, our model may underestimate or overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the indicator that was used for the 2017 MIPS performance period/2019 MIPS payment year. Finally, we excluded the MAQI participants with a MIPS exclusion for the 2019 MIPS performance period.

(b) Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN or APM entity) levels based on how data are submitted or at the APM Entity level if the clinician is part of a MIPS APM Entity scored under the APM scoring standard. To determine who is a MIPS APM participant, we used the latest 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data. We identified all clinicians in our eligible population who are in the 2019 predictive file and evaluated them as an APM Entity. We also evaluated clinicians as APM Entities if they are in our eligible population and associated with an APM Entity for the 2017 performance period but are no longer billing for Medicare (because they may have changed practices).[145] If a MIPS

[145] A total of approximately 222,000 clinicians were included in our model and scored using the APM scoring standard. These clinicians are represented in the individual and group eligibility

eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2017 MIPS performance period. If no data are submitted and the TIN/NPI is not associated with an APM Entity during the performance period, then the low-volume threshold is applied at the TIN/NPI level. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

Table 113 presents the estimated MIPS eligibility status and the associated PFS allowed charges for the 2020 MIPS performance period after using Quality Payment Program Year 1 data and applying the proposed policies for the 2020 MIPS performance period.

For the purposes of modeling, we made assumptions on group reporting to apply the low-volume threshold. One extreme and unlikely assumption is that no practices elect group reporting and the low-volume threshold would always be applied at the individual level. Although we believe a scenario in which only these clinicians would participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For this proposed rule model, we estimate there were approximately 221,000 clinicians [146] who would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 113, we identify clinicians under this assumption as having ''required eligibility.''

We anticipate that groups that submitted to MIPS as a group will continue to do so for the CY 2020 MIPS performance period. Using this group assumption and including those identified with MIPS APM entities in our scoring model, we increased the number of MIPS eligible clinicians by 566,000 clinicians. In Table 113, we identify these clinicians who do not meet the low-volume threshold individually but are anticipated to submit to MIPS as a group or MIPS APM as having ''group eligibility.'' With the availability of CY 2017 Quality Payment Program Year 1 data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data.

To model the opt-in policy finalized in the CY 2019 PFS final rule (83 FR 59735), we assumed that 33 percent of the clinicians who exceed at least one but not all low-volume threshold criteria and submitted data to CY 2017 MIPS performance period would elect to opt-in to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance. We believe this assumption of 33 percent opt-in participation is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment adjustment based on their performance. This 33 percent participation assumption is identified in Table 113 as ''Opt-In eligibility''. In this proposed rule analysis, we estimate an additional 31,000 clinicians would be eligible through this policy for a total MIPS eligible population of approximately 818,000. The leads to an associated $68 billion allowed PFS charges estimated to be included in the 2020 MIPS performance period.

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rows in Table 113 depending on whether they would have exceeded the low volume threshold as an individual or because they were part of an APM entity group submission.

[146] The count of 220,981 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (203,027 MIPS eligible clinicians), as well as those who did not participate (17,954 MIPS eligible clinicians).

TABLE 113: Description of MIPS Eligibility Status for CY 2022 MIPS Payment Year Using the CY 2020 PFS Proposed Assumptions**

		CY 2020 PFS Proposed Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	203,027	$48,306
	Do not participate in MIPS	17,954	$4,054
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	566,164	$14,145
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	31,246	$1,497
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**818,391***	68,002
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or(2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	385,635	$9,277
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	77,450	$403
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	202,684	$9,322
Total Number of Clinicians Not MIPS Eligible		665,769	19,002
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,484,160	87,004

* Estimated MIPS Eligible Population

** This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 13,000 clinicians and $2,763 million in PFS allowed charges).

*** Allowed charges estimated using 2016 and 2017 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

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There are approximately 386,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate or they elect to opt-in. We describe this group as ''Potentially MIPS eligible''. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate that the MIPS eligible clinician population could be as high as 1.2 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either

because they or their group are below the low-volume threshold on all three criteria (approximately 77,000) or because they are excluded for other reasons (approximately 203,000).

Since eligibility among many clinicians is contingent on submission to MIPS as a group, APM participation or election to opt-in, we will not know the number of MIPS eligible clinicians until the submission period for the 2020 MIPS performance period is closed. For this impact analysis, we used the estimated population of 818,391 MIPS eligible clinicians described above.

c. Estimated Impacts on Payments to MIPS Eligible Clinicians

(1) Summary of Approach

In sections III.K.3.c., III.K.3.d. and III.K.3.e. of this proposed rule, we present several proposals which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VI.E.10.c.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2022 MIPS payment year. We note that many of the MIPS policies from the CY 2019 Quality Payment Program final rule were only defined for the 2019 MIPS performance period and 2021 MIPS payment year (including the performance threshold, the additional performance threshold, the policy for redistributing the weights of the performance categories, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2020 MIPS performance period and 2022 MIPS payment year if there was no new regulatory action. Therefore, our impact analysis looks at the total effect of the proposed MIPS policy changes on the MIPS final score and payment adjustment for CY 2020 MIPS performance period/CY 2022 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VI.E.10.c.(2) of this proposed rule, we used the most recently available data from the Quality Payment Program which is generally data submitted for the 2017 MIPS performance period. We will use 2018 MIPS performance period data for the impact analysis in the final rule should that data become available.

The estimated payment impacts presented in this proposed rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues that clinicians earn would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2020 Quality Payment Program for this proposed rule, we used CY 2017 Quality Payment Program Year 1 performance period data. Our scoring model includes the 818,391 estimated number of MIPS eligible clinicians as described in section VI.E.10.b.(1)(b) of this RIA.

To estimate the impact of MIPS on eligible clinicians, we generally used the Quality Payment Program Year 1 submission data, including data submitted for the quality, improvement activities, and Promoting Interoperability (which was called advancing care information for the 2017 MIPS performance period) performance categories, CAHPS for MIPS and CAHPS for ACOs, the total per capita cost measure, Medicare Spending Per Beneficiary (MSPB) clinician measure and other data sets.[147] We calculated a hypothetical final score for the 2020 MIPS performance period/2022 MIPS payment year for each MIPS eligible clinician using score estimates described in this section for quality, cost, Promoting Interoperability, and improvement activities performance categories.

We did not model virtual groups since we had fewer than 10 virtual groups register for the 2019 performance period, which was not a sufficiently large number of virtual groups to model separately for this RIA. We will revisit modeling virtual groups separately once we receive virtual group submissions in future years.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a similar methodology described in the CY 2019 PFS final rule (83 FR 60053 through 60054) with the following modifications that reflect the newly proposed policies for the 2020 MIPS performance period and improvement to our modeling methodology. As proposed in section III.K.3.c.(1)(c)(ii) of this proposed rule, we increased the data completeness requirement for the CY 2020 performance period from 60 percent to 70 percent.

We also applied modifications that were previously finalized including the validation process that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77289 through 77291) and applying the topped out scoring cap that was finalized (82 FR 53721 through 53727) to the measures subject to the scoring cap for the 2019 MIPS performance period.

Finally, our model applied the APM scoring standard policies finalized in the CY 2019 PFS final rule (83 FR 59754) as modified by the proposals in section III.K.3.c.(5)(c)(i)(B) of this proposed rule to MIPS eligible clinicians identified as being scored as a MIPS APM in the eligibility section VI.E.10.b.(1)(b) of this proposed rule. As described in section III.K.3.c.(5)(c)(i)(B) of this proposed rule, we are proposing to apply a minimum score of 50 percent, or an 'APM Quality Reporting Credit', under the MIPS quality performance category for certain APM entities participating in MIPS. In our model, this proposed 'APM Quality Reporting Credit' was implemented for APM Entities that do not use Web Interface. We also propose in sections III.K.3.c.(5)(c)(i)(A) of this proposed rule to calculate an aggregated APM Entity quality score from submitted MIPS data by the participants in an APM Entity if the APM quality data cannot be used.

As described in section VI.E.10.b.(1).(b). of this proposed rule, we are using the 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data to identify who is an APM participant. In the case of MIPS APM entities that report Web Interface, if the APM Entity existed in 2017, we calculated a score based on the Web Interface submission from the 2017 performance period. If the APM Entity did submit Web Interface data for the 2017 performance period, we calculated an aggregate score based on individual

[147] 2016 PQRS and Value Modifier data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

submissions similar to how we estimate aggregate scores for MIPS APM entities that do not utilize Web Interface. If the APM Entity is new for 2019 (and therefore did not have the ability to submit Web Interface for the 2017 performance period), we used the average Web Interface score because we would anticipate the new APM Entities would report quality using Web Interface in the future. For MIPS APMs that do not utilize the Web Interface, we estimated the APM Entity quality performance category score by taking the higher of the group and individual quality scores for the clinicians in the APM Entity and calculating the average for the APM Entity. Clinicians were assigned a score of 0 if they did not submit quality data to MIPS. For the MIPS APMs that do not utilize Web Interface only, we then applied the proposed APM Quality Reporting Credit policy to add 50 percent to the MIPS quality score for APM Entities submitting to MIPS as proposed in section III.K.3.c.(5)(c)(i)(B) of this proposed rule. All quality performance category scores would be capped at 100 percent after receiving the 50 percent APM Quality Reporting Credit.

(b) Methodology To Estimate the Cost Performance Category Score

In section III.K.3.c(2)(b)(iii) of this proposed rule, we propose to add 10 episode-based measures to the cost performance category beginning with the 2020 performance period in addition to the 8 episode-based measures finalized in the CY 2019 PFS final rule (83 FR 59767). In section III.K.3.c.(2)(b)(v) of this rule, we propose to revise the total per capita cost and MSPB clinician measures.

We estimated the cost performance category score using all measures included in section III.K.3.c.(2)(b)(viii) of this proposed rule. The total per capita cost measure performance was estimated based on the proposed revised measure using claims data from October 2016 through September 2017. The MSPB clinician measure performance was estimated based on the proposed revised measure using claims data from January through December of 2017. For the episode-based measures, we used the specifications for the 8 episode-based measures finalized in the CY 2019 PFS final rule (83 FR 35902 through 35903), the proposed specifications for the 10 new episode-based measures discussed in section III.K.3.c.(2)(b)(iii) of this proposed rule and claims data from January through December of 2017. Cost measures scored if the clinicians or groups met or exceed the case volume: 20 for the total per capita cost measure, 35 for MSPB clinician, 10 for procedural episode-based measures, and 20 for acute inpatient medical condition episode-based measures. The cost measures are calculated for both the TIN/NPI and the TIN, except for the lower gastrointestinal hemorrhage measure, which we propose in section III.K.3.c.(2)(vi)(B) of this proposed rule to calculate only for groups. For clinicians participating as individuals, the TIN/NPI level score was used if available and if the minimum case volume was met. For clinicians participating as groups, the TIN level score was used, if available, and if the minimum case volume was met. For clinicians with no measures meeting the minimum case requirement, we did not estimate a score for the cost performance category, and the weight for the cost performance category was reassigned to the quality performance category. The raw cost measure scores were mapped to scores on the scale of 1–10, using benchmarks based on all measures that met the case minimum and if the group or clinician exceeded the low-volume threshold during the relevant performance period. For the episode-based cost measures, separate benchmarks were developed for TIN/NPI level scores and TIN level scores. For each clinician, a cost performance category score was calculated as the average of the measure scores available for the clinician.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As finalized in the CY2019 PFS final rule (83 FR 59856), we determine the eligible clinician's MIPS cost and quality performance category score in facility-based measurement based on Hospital VBP Program Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. We estimate the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763). In section III.K.3.d.(1)(c) of this proposed rule, we are only proposing technical changes for clarity and those changes do not affect the facility-based policies. In the CY 2019 PFS final rule (83 FR 60054 through 60055), we were unable to incorporate the facility-based logic fully into our model. For this proposed rule, we have new datasets that allow us to more completely model facility-based measurement.

We used data from the feedback reports for the first determination period for the 2019 performance period, which is from October 1, 2017 to September 30, 2018 to attribute clinicians and groups to hospitals and assign the specific Hospital VBP Program Total Performance Score. Although the time period for facility-based eligibility does not align with the MIPS eligibility and performance period data, these facility-based eligibility data were used because we did not have attribution data available for the matching performance period and the use of actual attribution data was preferable to using proxy data. If a Hospital VBP Program Total Performance Score could not be assigned to a clinician, in instances in which the attributed facility does not participate in the Hospital VBP program, that clinician was determined as not eligible for facility-based measurement and assumed to participate in MIPS via other methods. In some cases, a group or clinician may have changed practices and would not have an associated facility-based indicator in the feedback reports (because the feedback reports used a different time period). In those cases, if the TIN or TIN–NPI was facility-based in the 2017 MIPS performance period, we estimated a facility-based score by taking the median MIPS quality and cost performance score. We are not requiring eligible clinicians to opt-in to facility-based measurement; it is possible that a MIPS eligible clinician or a group is automatically eligible for facility-based measurement, but they participate in MIPS as an individual or a group. In these cases, we used the higher combined quality and cost performance category score, as reflected in the final score, from facility-based scoring compared to the combined quality and cost performance category score from MIPS submission-based scoring.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimated the Promoting Interoperability performance category score using the methodology described in the CY 2019 PFS final rule (83 FR 60055) with the following modifications that reflect the newly proposed policies for the 2020 MIPS performance period.

In section III.K.3.c.(4)(d)(i)(B)(aa) of this proposed rule, we proposed to modify the Query of PDMP measure to a yes/no response. The Query of PDMP measure was not modeled because the measure was not available in the 2017 MIPS performance period submissions data.

In section III.K.3.c.(4)(f)(iii) of this proposed rule, we proposed to revise the definition of hospital-based MIPS eligible clinician to include groups and virtual groups. We also proposed that a

hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician. In section III.K.3.c.(4)(f)(iv) of this proposed rule, we proposed revisions to also account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician such that the group or virtual group only has to meet a threshold of more than 75 percent. Also, as described in sections III.K.3.c.(4)(f)(iii) and III.K.3.c.(4)(f)(iv) of this proposed rule, we proposed to assign a zero percent weight for the Promoting Interoperability performance category for groups defined as hospital-based and non-patient facing, and redistribute the points associated with the Promoting Interoperability performance category to another performance category or categories. Therefore, in our impact analysis model, a group was only assigned a zero percent weight for the Promoting Interoperability performance category and the points for Promoting Interoperability performance category was redistributed if: (1) All the TIN/NPIs were eligible for reweighting as established at § 414.1380(c)(2)(iii) for MIPS eligible clinicians submitting data as a group or virtual group, or (2) the group met the proposed revised definition of a hospital-based MIPS eligible clinician as proposed in section III.K.3.c.(4)(f)(iii) of this proposed rule or the definition of a non-patient facing MIPS eligible clinician, as proposed in section III.K.3.c.(4)(f)(iv) of this proposed rule, as defined in § 414.1305. We also incorporated into our model the proposed policy to continue automatic reweighting for NPs, PAs, CNSs and CRNAs, physical therapists, occupational therapist, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals as described in sections III.K.3.c.(4)(f)(i) and III.K.3.c.(4)(f)(ii) of this proposed rule.

In our model, for the APM participants identified in section VI.E.10.b.(1).(b).of this proposed rule, we simulated MIPS APM Entity scores by using submitted Promoting Interoperability data by groups or individuals that we identified as being in a MIPS APM to calculate an APM Entity score.

All other proposed policies for the Promoting Interoperability performance category described in section III.K.3.c.(4) of this proposed rule did not impact our modeling methodology for this performance category because either the data were not available in the 2017 MIPS performance period submissions data or the proposed changes reflect the modeling strategy previously used and described in the CY 2019 PFS final rule (83 FR 60055). For example, since the Verify Opioid Treatment Agreement measure was not modeled in the CY 2019 PFS final rule (83 FR 60055) because the measure was not available in the 2017 MIPS performance period submissions data, the proposed removal of this measure did not impact our impact analysis methodology for this proposed rule.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2017 Quality Payment Period Year 1 data and APM participation in the 2017 MIPS performance period. In section III.K.3.c.(3)(d)(iii) of this proposed rule, we are proposing to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent for the improvement activities performance category beginning with the CY 2020 performance year and future years. We did not incorporate this proposed change into our model because we did not have the information to model this proposal. For the APM participants identified in section VI.E.10.b.(1)(b) of this proposed rule, we assigned an improvement activity performance category score of 100 percent.

Clinicians and groups not participating in a MIPS APM were assigned their CY 2017 Quality Payment Program Year 1 improvement activities performance category score.

(f) Methodology To Estimate the Complex Patient Bonus

In section III.K.3.d.(2)(a) of this proposed rule, we are proposing to continue the complex patient bonus. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model used the complex patient bonus information calculated for the 2018 performance period data, because this variable was available in time for the publication of this proposed rule. If the clinician did not have a complex patient bonus score from the 2018 performance period data (because the bonus was from a different performance period), we proxied a score using the methods described in the CY 2019 PFS final rule (83 FR 59869) to supplement the gap in data.

(g) Methodology To Estimate the Final Score

As proposed in sections III.K.3.c.(1)(b), III.K.3.c.(2)(a), and summarized in section III.K.3.d.(2)(b) of this proposed rule, our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for the Promoting Interoperability due to a significant hardship or other type of exception, the weight for the Promoting Interoperability performance category was redistributed to the quality performance category. For MIPS eligible clinicians who did not have a cost performance category score, the weight for the cost performance category was redistributed to the quality and Promoting Interoperability performance categories.

In our scoring model, we did not address scenarios where a zero percent weight would be assigned to the quality performance category or the improvement activities performance category. We applied the remaining reweighting scenarios described in detail in section III.K.3.d.(2)(b)(ii) of this proposed rule and in the CY 2019 PFS Final Rule (83 FR 59871 through 83 FR 59878).

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we applied a hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available (for example if a clinician qualifies for a score for an APM entity and a group score, we select the APM entity score).

We then calculated the parameters of an exchange function in accordance

with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using a performance threshold of 45 points and the additional performance threshold of 80 points (as proposed in sections III.K.3.e.(2) and III.K.3.e.(3) of this proposed rule). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered professional services furnished by the MIPS eligible clinician. We considered other performance thresholds which are discussed in section VI.F.2. of this RIA.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $586 million would be redistributed through budget neutrality and that $500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The model further estimates that the maximum positive payment adjustments are 5.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance.

Table 114 shows the impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS. We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger sized practices. In aggregate, the cohort of clinicians in small practices participating in MIPS and who submit to MIPS receive a 0.9 percent increase in total paid amount, which is lower than the comparative payment increases received by the cohort of MIPS eligible clinicians in larger-sized practices. Table 114 also shows that 87.3 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. We want to highlight that we are using 2017 performance period submissions data for these calculations, and it is likely that there will be changes that we cannot account for at this time. For example, the 2017 performance period was the first year of the program, and it was considered a ''Pick Your Pace'' year of participation. With ''Pick Your Pace'', clinicians could begin slowly participating in MIPS at their own pace by determining how much data to submit and their level of participation. Specifically, the performance threshold was set at 3 points, and submission of one quality measure or attesting to one improvement activity would allow a clinician to meet or exceed the performance threshold. In the second and third years of the program, the performance thresholds increased, along with the data submission requirements to avoid a negative payment adjustment. At this time, we are not able to estimate the impact of these policy changes using Year 1 performance period data, but we anticipate having additional information based on 2018 (year 2) data submissions when conducting the impact analysis for the final rule.

The combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because these clinicians do not all receive a final score of zero. Indeed, some MIPS eligible clinicians that do not submit data to MIPS may receive final scores above zero through performance on the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS. Among those who we estimate would not submit data to MIPS, 90 percent are in small practices (16,116 out of 17,954 clinicians who do not submit data). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs. We also note this participation data is generally based off participation for the 2017 performance period and that participation may change for the 2020 performance period. As stated above, the 2017 performance period was the first year of MIPS, which was a ''Pick Your Pace'' year, and we believe that the level of participation and amount of data submitted will likely change in ensuing years. For example, we note in section III.K.1.a. of this proposed rule that we have published participation rates for the 2018 performance period and those rates differ from the 2017 performance period participation rates, where a slight increase in participation was observed. We did not have the submission data in time for this analysis, but we intend to update our data for the final rule.

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TABLE 114: MIPS Estimated Payment Year 2022 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*[a]

Practice Size*	Number of MIPS eligible clinicians	Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent MIPS Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent MIPS Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**
Among those submitting data* **					
1) 1-15	145,457	76.5%	41.2%	23.5%	0.9%
2) 16-24	42,691	81.9%	40.8%	18.1%	1.1%
3) 25-99	189,603	85.3%	44.4%	14.7%	1.3%
4) 100+	422,686	92.5%	62.4%	7.5%	2.1%
Overall	**800,437**	87.3%	53.2%	12.7%	1.4%
Among those not submitting data					
1) 1-15	16,116	0.0%	0.0%	100.0%	-8.1%
2) 16-24	674	0.0%	0.0%	100.0%	-8.2%
3) 25-99	953	0.0%	0.0%	100.0%	-8.3%
4) 100+	211	0.0%	0.0%	100.0%	-8.5%
Overall	17,954	**0.0%**	**0.0%**	**100.0%**	-8.2%

*Practice size is the total number of TIN/NPIs in a TIN.

**2016 and 2017 data used to estimate 2020 performance period payment adjustments. Payments estimated using 2016 and 2017 dollars trended to 2022. The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

***Includes facility-based clinicians whose quality data is submitted through hospital programs.

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e. Potential Costs of Compliance With the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians

(1) Potential Costs of Compliance With Promoting Interoperability Performance Category

In section III.K.3.c.(4)(d)(i)(B)(aa) of this proposed rule, we propose to allow clinicians and groups to satisfy the optional bonus Query of PDMP measure by submitting a ''yes/no'' attestation, rather than reporting a numerator and denominator. As discussed in the Collection of Information section of this proposed rule, we are not changing our burden assumptions to account for this proposal due to a lack of information regarding the number of clinicians reporting bonus measures combined with our currently approved burden estimates being based only on the reporting of required measures. However, we do believe that for clinicians or groups who report this measure, there will be a reduction in reporting burden compared to what would have been required to submit the measure without this proposed change related to the elimination of the need to perform calculations prior to submitting a numerator and denominator. As data availability allows, we will reassess the inclusion of this burden in the Collection of Information in the future.

In sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this rule, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In the Collection of Information section, we discussed the potential burden reduction associated with simplifying MIPS reporting for clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data. We believe it is also possible that some MIPS eligible clinicians may elect to begin utilizing qualified registries or QCDRs as a result this proposed policy and its potential for simplifying their MIPS reporting combined with the benefits of improving the quality of care provided to their patients. We do not have information with which to estimate the number of clinicians who may pursue this option, therefore we cannot quantify the associated costs, cost savings, and benefits consistent with the CY 2018 Quality Payment Program final rule (82 FR 53946).

(2) Potential Costs of Compliance With Improvement Activities Performance Category

In section III.K.3.c.(3)(d)(iii) of this proposed rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. In addition, we are proposing changes to the

Improvement Activities Inventory to: (1) Establish removal factors to consider when proposing to remove improvement activities from the Inventory; (2) remove 15 improvement activities for the CY 2020 performance period and future years contingent on our proposed removal factors being finalized; (3) modify 7 existing improvement activities for the CY 2020 performance period and future years; and (4) add two new improvement activities for the CY 2020 performance period and future years.

Given groups' familiarity with the improvement activities in the Improvement Activities Inventory, we assume that a group would find applicable and meaningful activities to complete that are not specific to practice size, specialty, or practice setting and would apply to at least 50 percent of individual MIPS eligible clinicians in the group. Therefore, an increase in the minimum threshold for a group to receive credit for the improvement activities performance category should not present additional complexity or burden. We also anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies established in this proposed rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). Most of the improvement activities in Improvement Activities Inventory remain unchanged for the 2020 MIPS performance period and most clinicians are likely to have selected improvement activities that were unaffected by the changes. Of the activities that were removed, modified, or added, many were duplicative which means many clinicians or groups would be able to continue the activity, but it would be reported under a different activity in the Improvement Activities Inventory.

Our proposal to establish removal factors when proposing to remove improvement activities from the Improvement Activities Inventory would provide guidance for clinicians or groups on the considerations for the removal of improvement activities and would not present additional burden. The proposed changes to the Improvement Activities Inventory that include the modification, removal, and addition of improvement activities provide clarity, avoid duplication, and provide more options for clinicians to select improvement activities that are appropriate for their clinical practice and would not present additional burden. Furthermore, in this proposed rule, we are proposing to end and remove the Study on Factors Associated with Reporting Quality Measures beginning with the 2020 MIPS performance period. In the CY 2019 PFS final rule, we finalized a sample size of 200 clinicians, each of which completed a 15-minute survey both prior to and after submitting MIPS data (83 FR 60058). As a result of ending the study, we estimate a reduction in burden of 100 hours and $20,286 (200 clinicians × 0.5 hours × $202.86).

f. Potential Costs of Compliance for Third Party Intermediaries

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at § 414.1400(a)(2) (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. As previously discussed in section III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of this proposed rule, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: Quality, improvement activities, and Promoting Interoperability. In section III.K.3.g.(1), we further state that we anticipate using the QCDR and qualified registry self-nomination vetting process to assess which of these entities will be subject to the proposed requirement to support reporting the Promoting Interoperability performance category and which entities would be subject to an exception based on which clinician types they serve and whether those clinician types are eligible for reweighting of the Promoting Interoperability performance category as discussed in section III.K.3.c.(4). Based on our review of qualified registries and QCDRs approved to submit data for the 2019 MIPS performance period, 70 percent of qualified registries and 72 percent of QCDRs already offer support for the quality, improvement activities, and Promoting Interoperability performance categories. We believe this proposal could result in the remaining qualified registries and QCDRs incurring additional costs to upgrade information technology systems in order to make this ability available to clinicians, with less cost incurred by entities who would be subject to an exception for the Promoting Interoperability performance category. However, given that each of these entities and their information technology systems are unique, and there is no method of determining which entities may have already begun the process of developing this ability, we are unable to determine the impact of transitioning from allowing this ability as an option to requiring it. Also, given that the majority of these entities have already begun offering the ability to submit data on behalf of the improvement activities and Promoting Interoperability performance categories, we assume they have done so because they believe the benefits outweigh the costs and is therefore, in their best financial interests to do so.

We are also proposing in section III.K.3.g.(3)(a)(ii) of this proposed rule, beginning with the 2021 performance period, to require qualified registries and QCDRs to provide the following as part of the performance feedback given at least 4 times a year: Feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. As finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77367 through 77386 and 82 FR 53812), qualified registries and QCDRs are required to provide feedback on all of the MIPS performance categories that the qualified registry or QCDR reports at least 4 times a year. Given that we are not proposing a significant change but are instead proposing to modify and strengthen the existing policy, we do not anticipate a significant increase in cost or effort for Third Party Intermediaries to comply with this proposal. In alignment with our proposal above, we are also proposing to require QCDRs to provide services to clinicians and groups to foster improvement in the quality of care provided to patients, by providing educational services in quality improvement and leading quality improvement initiatives. Similar to the requirement to support submission of Promoting Interoperability and improvement activity data, we believe this proposal could result in QCDRs incurring additional costs. We are unable to create a baseline of current service offerings for each QCDR, which would be needed in order to determine

the incremental costs associated with providing any additional services required by this proposal. We believe that by offering these services, additional MIPS eligible clinicians may be encouraged to utilize these entities, thereby increasing membership and potentially offsetting some of the costs the QCDR would have to incur.

In section III.K.3.g.(3)(c)(i)(B)(cc), we are proposing that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are proposing in section III.K.3.g.(3)(c)(i)(B)(dd) to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. The testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type.[148] Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported.[149] While we understand the proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval while others do not. This variability makes it difficult to estimate the incremental impact of this regulation.

In section III.K.3.g.(3)(c)(i)(A)(bb) of this rule, we are proposing to amend § 414.1400 to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we have little insight into both the specific terms and frequency of agreements made between entities, we are unable to account for the financial impact of licensing QCDR measures for each QCDR. In aggregate across all QCDRs, the financial impact would be zero as fees paid by one QCDR will be collected by another QCDR.

In section III.K.3.g.(3)(c)(i)(B)(ee) of this rule, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for the financial impact of measure harmonization, as the process and outcomes will likely vary substantially depending on a number of factors, including: Extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

We understand that some QCDRs may believe the proposals to require measure harmonization and encourage QCDRs to license their measures to other QCDRs as a consideration for measure approval may result in a reduced ability for QCDRs to differentiate themselves in the marketplace. We note that in addition to the suite of measures offered by a QCDR and their relevance to individual clinicians and groups, ease of incorporating a QCDR's measures into existing practice workflows, as well as integration into broader quality improvement programs are two examples of distinguishing characteristics for clinicians to consider when selecting a QCDR. In addition, clinicians may also consider cost (if any); recommendations, support, or endorsements from specialty societies; the number of other users submitting data to the QCDR; the specific educational services and quality improvement initiatives offered; and the specific performance feedback information provided as part of the required reports provided at least 4 times a year. We believe that the impact these proposals may have on the perceived differentiated value of certain QCDRs is counterbalanced by the need to promote more focused quality measure development towards outcomes that are meaningful to patients, families and their providers.

In this proposed rule, we are proposing to formalize a number of factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2020 performance period and future years. With regard to approving QCDR measures, we are proposing the following: (1) 2-year QCDR measure approval process, and (2) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds.

As discussed in section III.K.3.g.(3)(c)(ii)(B), we are proposing to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The 2-year approvals would be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: Topped

[148] *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx.*

[149] Schuster, Onorato, and Meltzer. ''Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy'', Journal of the American Medical Association. 2017; 318(13):1219–1220. *https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1.*

out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this will result in reduced burden for QCDRs as they will no longer be required to submit each measure for approval annually. However, because we are unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the impact on future burden associated with QCDRs submitting measures for approval. Beginning with the 2021 performance period, we are proposing that in instances where an existing QCDR measure has been in MIPS for 2 years and has failed to reach benchmarking thresholds due to low adoption, where the QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may submit to CMS a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the proposed criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the impact associated with this proposal.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of this proposed rule, beginning with the 2021 performance period and future years, we are proposing that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measures (as found in section III.K.3.c.(3) of this proposed rule), (b) improvement activities (as found in Appendix 2: Improvement Activities Tables), or (c) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of this proposed rule). We do not assume any additional impact beyond the 1 hour per QCDR measure discussed in the Collection of Information section.

g. Assumptions & Limitations

We note several limitations to our estimates of MIPS eligible clinicians' eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2022 MIPS payment year. We based our analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*),[150] participant lists using the 2019 predictive APM Participation List, which contains the 2018 fourth snapshot and any additional TIN/NPIs until January 15, 2019, CY 2017 Quality Payment Program Year 1 data and CAHPS for ACOs. The scoring model results presented in this proposed rule assume that CY 2017 Quality Payment Program Year 1 data submissions and performance are representative of CY 2020 Quality Payment Program data submissions and performance. The estimated performance for CY 2020 MIPS performance period using Quality Payment Program Year 1 data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2017 MIPS performance period/2019 MIPS payment year was significantly lower (3 out of 100 points) than the performance threshold for the 2020 MIPS performance period/2022 MIPS payment year (45 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that 33 percent of the opt-in eligible clinicians that participated in the CY 2017 Quality Payment Program Year 1 would elect to opt-in to the MIPS program. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policies.

There are additional limitations to our estimates: (1) Because we used historic data, we assumed participation in the three performance categories in MIPS Year 1 would be similar to MIPS Year 4 performance; and (2) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 114. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our proposed policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 110 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty).

1. Alternatives Considered Related to Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

We considered several possibilities for pricing the oral medications, namely methadone and buprenorphine (oral), included in the OTP payment bundles. As described in section II.G. of this proposed rule, we are proposing to use ASP-based payment for oral OTP drugs; however, in the event we do not receive manufacturer-submitted ASP pricing data for these drugs, we are also considering several other alternative pricing mechanisms to determine the pricing of the drug components of the bundles that include these medications, including the methodology under Section 1847A of the Act; Medicare Part D Prescription Drug Plan Finder data; WAC; and NADAC data. For methadone, we also consider an alternative using the TRICARE payment rate for methadone in its OTP bundled payment. In Table 14, we display the estimated initial drug payment rates for the proposed pricing approach for the oral drugs and each of the alternatives, based on data files posted at the time of the drafting of this proposed rule. We used the TRICARE payment rate for methadone to estimate the payment rates for the methadone payment bundles and NADAC data to estimate the payment rates for the buprenorphine (oral) payment bundles, and to derive the impact estimates.

For methadone, we believe using Medicare Part D Prescription Drug Plan Finder Data to price the medication would have minimal impact on the RIA estimate since the rate is very close to the TRICARE payment rate. Using WAC-based pricing for methadone would likely increase the impact estimate marginally since WAC-based pricing is slightly higher than the TRICARE payment rate. Since NADAC pricing for methadone is significantly less than the TRICARE payment rate, using NADAC pricing would significantly decrease the impact estimates, especially because the

[150] The time period for this eligibility file (September 1, 2016 to August 31, 2017) maximizes the overlap with the performance data in our model.

vast majority of patients receiving OUD treatment services at OTPs are receiving methadone.

For buprenorphine (oral), the Medicare Part D Prescription Drug Plan Finder data is very similar to NADAC pricing. Therefore we believe there would be minimal changes in the estimated impacts from using this alternative data source. Since WAC-based pricing is slightly higher than NADAC pricing, we note that using WAC-based pricing would increase the estimated impacts marginally.

We also considered several alternatives for the update factor used in updating the payment rates for the non-drug component of the bundled payment for OUD treatment services, including the Bureau of Labor Statistics Consumer Price Index for All Items for Urban Consumers (CPI–U) (Bureau of Labor Statistics #CUUR0000SA0 (*https://www.bls.gov/cpi/data.htm*)) and the IPPS hospital market basket reduced by the multifactor productivity adjustment. Based on a CMS forecast of projected rates, we believe that the projected MEI and CPI–U rates are anticipated to be similar, and thus using the CPI–U as an update factor would have minimal effect on estimated impacts. Since the projected IPPS hospital market basket rate is generally higher than the projected MEI rate, using the IPPS hospital market basket rate would result in higher estimated impacts.

2. Alternatives Considered Related to Payment for E/M Services

In developing our proposed policies for office/outpatient E/M visits effective January 1, 2021, we considered a number of alternatives. For reasons discussed in section II.P. of this proposed rule, we did not include either the extended office/outpatient E/M HCPCS code GPR01 or the single blended payment rates for combined visit levels 2 through 4 that were finalized in the CY 2019 final rule for CY 2021 in our considerations. Our alternatives also did not include the revaluation of global surgical services, as recommended by the AMA RUC, which incorporated the revised office/outpatient E/M code values. We note that in all of the alternatives we considered, the valuation for all codes in the office/outpatient E/M code set would increase. Therefore, all specialties for whom the office/outpatient codes represent a significant portion of their billing would also see payment increases while those specialties who do not report those codes would see overall payment decreases. Any variation in the magnitude of the increases or decreases are a result of a specialties overall billing patterns.

We did, however, consider proposing to eliminate both add-on codes, HCPCS code GCG0X and HCPCS code GPC1X, that were finalized in the CY 2019 final rule for CY 2021. Our stated rationale in the CY 2019 final rule for developing HCPCS code GPC1X (83 FR 59625 through 59653) was to more accurately account for the type and intensity of E/M work performed in primary care-focused visits beyond the typical resources reflected in the single payment rate for the levels 2 through 4 visits. The reason for finalizing HCPCS code GCG0X, as stated in the CY 2019 FR (83 FR 59625 through 59653) GCG0X was to reflect additional resource costs for inherently complex services that are non-procedural. We considered whether these two add-on codes would still be necessary in the context of the revised descriptors and valuations for office/outpatient E/M services. We considered an alternative, therefore, in which we adopted the RUC's recommended values but excluded the two HCPCS add-on G-codes. In reviewing the results of this policy option, we observed that our concerns about capturing the work associated with visits that are part of ongoing, comprehensive primary care and/or care management for patients having a single, serious, or complex chronic condition were still present. The specialty level impacts associated with this alternative are displayed in Table 115. The specialties that benefited most from this alternative, such as Endocrinology and Rheumatology, are those that primarily bill levels 3–5 established patient office/outpatient E/M visits, as those visit levels had the greatest increases in valuation among the overall office/outpatient E/M code set.

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TABLE 115: Estimated Specialty Specific Impacts of Accepting the RUC Recommended Values but Deleting Both HCPCS G codes GCG0X and GPC1X if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	6%
Anesthesiology	$1,993	-3%	-1%	0%	-4%
Audiologist	$70	-3%	-1%	0%	-4%
Cardiac Surgery	$279	-4%	-1%	-1%	-5%
Cardiology	$6,595	1%	1%	0%	1%
Chiropractor	$750	-4%	-2%	-1%	-7%
Clinical Psychologist	$787	-4%	0%	0%	-4%
Clinical Social Worker	$781	-4%	1%	0%	-4%
Colon And Rectal Surgery	$162	-1%	0%	0%	-1%
Critical Care	$346	-3%	-1%	0%	-3%
Dermatology	$3,541	1%	2%	-1%	2%
Diagnostic Testing Facility	$697	0%	-3%	0%	-3%
Emergency Medicine	$3,021	-3%	-1%	1%	-4%
Endocrinology	$488	7%	3%	1%	10%
Family Practice	$6,019	5%	2%	0%	7%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	3%	1%	0%	5%
General Surgery	$2,031	-1%	0%	0%	-2%
Geriatrics	$187	1%	1%	0%	2%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,673	5%	2%	1%	8%
Independent Laboratory	$592	-2%	0%	0%	-2%
Infectious Disease	$640	-2%	-1%	0%	-3%
Internal Medicine	$10,507	1%	1%	0%	2%
Interventional Pain Mgmt	$885	2%	2%	0%	4%
Interventional Radiology	$432	-2%	-2%	0%	-4%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	-1%	0%	0%	-1%
Neurology	$1,503	1%	4%	0%	6%
Neurosurgery	$802	-2%	0%	-1%	-3%
Nuclear Medicine	$50	-2%	0%	0%	-2%
Nurse Anes / Anes Asst	$1,291	-5%	-1%	0%	-6%
Nurse Practitioner	$4,503	2%	1%	0%	4%
Obstetrics/Gynecology	$620	2%	2%	0%	4%
Ophthalmology	$5,398	-3%	-4%	0%	-7%
Optometry	$1,325	0%	-2%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-1%
Orthopedic Surgery	$3,734	0%	1%	0%	1%
Other	$34	-1%	-1%	0%	-2%
Otolarngology	$1,225	2%	1%	0%	3%
Pathology	$1,203	-3%	-2%	0%	-5%
Pediatrics	$62	2%	1%	0%	3%
Physical Medicine	$1,110	0%	0%	0%	0%
Physical/Occupational Therapy	$4,248	-3%	-2%	0%	-5%
Physician Assistant	$2,637	2%	1%	0%	4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Plastic Surgery	$369	-1%	0%	-1%	-2%
Podiatry	$1,998	2%	2%	0%	4%
Portable X-Ray Supplier	$94	-1%	-1%	0%	-3%
Psychiatry	$1,120	2%	1%	0%	3%
Pulmonary Disease	$1,658	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-1%	-1%	0%	-2%
Radiology	$4,971	-3%	-2%	0%	-5%
Rheumatology	$534	6%	3%	1%	9%
Thoracic Surgery	$352	-3%	-1%	0%	-5%
Urology	$1,739	2%	2%	0%	5%
Vascular Surgery	$1,203	-1%	-2%	0%	-3%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

We also considered, as an alternative, proposing CMS refinements to the RUC recommendations for two of the CPT codes. Consistent with our generally established policies for reviewing work RVUs recommended by the RUC, we observed that the increase in work RVU for CPT codes 99212 and 99214 (levels 2 and 4 for established patients) seemed disproportionate to the increase in total time for these services, particularly in comparison with the work to time relationships among the other seven E/M code revaluations. For CPT code 99212, we observed that the total time for furnishing this service increased by 2 minutes (13 percent increase), but that the recommended work RVU increased by nearly 50 percent from 0.48 to 0.70. We reviewed other CPT codes with similar times as the survey code and identified a potential crosswalk to CPT code 76536 (*Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation*), with a work RVU of 0.56. We therefore considered decreasing the work RVU for CPT code 99212 to 0.56. For CPT code 99214, the total time increased from 40 to 49 minutes, which is a 23 percent change, while the work RVU increased from 1.50 to 1.92 (28 percent increase). We considered a crosswalk to CPT code 73206 (*Computed tomographic angiography, upper extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing*), with a work RVU of 1.81 and total time of 50 minutes. The refinements we considered for the RUC recommendations are shown in Table 116.

TABLE 116—CURRENT, RUC RECOMMENDED AND CMS REFINED OFFICE/OUTPATIENT E/M WORK RVUS

CPT/HCPCS	Current work RVU (current)	RUC-recommended work RVU	Alternative: CMS-refined work RVU
99201	0.48	NA	NA
99202	0.93	0.93	0.93
99203	1.42	1.6	1.6
99204	2.43	2.6	2.6
99205	3.17	3.5	3.5
99211	0.18	0.18	0.18
99212	0.48	0.7	0.56
99213	0.97	1.3	1.3
99214	1.5	1.92	1.81
99215	2.11	2.8	2.8
99XXX	NA	0.61	0.5
GPC1X	0.25	NA	0.33
GCG0X	0.25	NA	0.33

Table 117 illustrates the specialty level impacts of refining the RUC recommendations. Under this alternative those specialties who frequently bill CPT code 99212 or CPT code 99214, such as dermatology and family practice, respectively, experience more modest increases relative to other alternatives.

TABLE 117: Estimated Specialty Specific Impacts of CMS Refined Values if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	6%
Anesthesiology	$1,993	-3%	-1%	0%	-4%
Audiologist	$70	-2%	-1%	0%	-4%
Cardiac Surgery	$279	-3%	-1%	0%	-5%
Cardiology	$6,595	1%	1%	0%	1%
Chiropractor	$750	-3%	-2%	-1%	-6%
Clinical Psychologist	$787	-4%	0%	0%	-3%
Clinical Social Worker	$781	-4%	1%	0%	-3%
Colon And Rectal Surgery	$162	-1%	0%	0%	-1%
Critical Care	$346	-2%	-1%	0%	-3%
Dermatology	$3,541	1%	2%	-1%	2%
Diagnostic Testing Facility	$697	0%	-3%	0%	-3%
Emergency Medicine	$3,021	-3%	-1%	1%	-3%
Endocrinology	$488	5%	2%	1%	8%
Family Practice	$6,019	4%	2%	1%	6%
Gastroenterology	$1,713	0%	0%	-1%	-1%
General Practice	$405	3%	1%	0%	4%
General Surgery	$2,031	-1%	0%	0%	-2%
Geriatrics	$187	1%	1%	0%	2%
Hand Surgery	$226	0%	1%	0%	1%
Hematology/Oncology	$1,673	5%	2%	1%	8%
Independent Laboratory	$592	-2%	0%	0%	-2%
Infectious Disease	$640	-2%	0%	0%	-2%
Internal Medicine	$10,507	1%	1%	0%	2%
Interventional Pain Mgmt	$885	2%	2%	1%	4%
Interventional Radiology	$432	-1%	-2%	0%	-4%
Multispecialty Clinic/Other Phys	$148	0%	0%	0%	0%
Nephrology	$2,164	-1%	0%	0%	-1%
Neurology	$1,503	1%	4%	0%	5%
Neurosurgery	$802	-1%	0%	-1%	-3%
Nuclear Medicine	$50	-2%	0%	0%	-2%
Nurse Anes / Anes Asst	$1,291	-4%	-1%	0%	-5%
Nurse Practitioner	$4,503	2%	1%	0%	4%
Obstetrics/Gynecology	$620	2%	2%	0%	4%
Ophthalmology	$5,398	-3%	-4%	0%	-7%
Optometry	$1,325	0%	-2%	0%	-2%
Oral/Maxillofacial Surgery	$71	0%	0%	-1%	-1%
Orthopedic Surgery	$3,734	0%	1%	0%	1%
Other	$34	-1%	-1%	0%	-2%
Otolarngology	$1,225	2%	2%	0%	3%
Pathology	$1,203	-3%	-2%	0%	-5%
Pediatrics	$62	2%	1%	0%	3%
Physical Medicine	$1,110	0%	0%	0%	1%
Physical/Occupational Therapy	$4,248	-3%	-2%	0%	-5%
Physician Assistant	$2,637	2%	1%	0%	4%
Plastic Surgery	$369	-1%	0%	-1%	-2%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Podiatry	$1,998	2%	2%	0%	4%
Portable X-Ray Supplier	$94	-1%	-1%	0%	-2%
Psychiatry	$1,120	1%	1%	0%	3%
Pulmonary Disease	$1,658	0%	0%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-1%	-1%	0%	-2%
Radiology	$4,971	-3%	-2%	-1%	-5%
Rheumatology	$534	5%	2%	1%	8%
Thoracic Surgery	$352	-3%	-1%	0%	-4%
Urology	$1,739	2%	2%	0%	5%
Vascular Surgery	$1,203	-1%	-2%	0%	-3%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

We also considered an alternative that reflected CMS refinements to the three CPT codes as described above and also included the consolidated, redefined and revalued HCPCS add-on G code, GPC1X.

Table 118 illustrates the specialty level impacts associated with making refinements to the RUC recommended values for the office/outpatient E/M code set and also making separate payment for HCPCS add-on code GPC1X. These impacts are similar to what we are proposing, with slight less positive impacts for those specialties who bill CPT codes 99212 or 99214.

TABLE 118: Estimated Specialty Specific Impacts of CMS Refined Values with HCPCS add-on G code GPC1X if Implemented in CY 2020

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$236	3%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-6%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-7%
Cardiology	$6,595	1%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-6%	0%	0%	-6%
Clinical Social Worker	$781	-6%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	0%	0%	-3%
Critical Care	$346	-4%	-1%	0%	-5%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	0%	-3%	0%	-4%
Emergency Medicine	$3,021	-5%	-2%	1%	-6%
Endocrinology	$488	10%	4%	1%	15%
Family Practice	$6,019	7%	3%	1%	11%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	7%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	1%	2%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	7%	4%	1%	12%
Independent Laboratory	$592	-2%	-1%	0%	-4%
Infectious Disease	$640	-2%	0%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-2%	-3%	0%	-5%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-3%	0%	0%	-4%
Nurse Anes / Anes Asst	$1,291	-6%	-2%	0%	-8%
Nurse Practitioner	$4,503	4%	3%	0%	7%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-9%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-3%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolarngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-4%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	5%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-4%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-2%	-1%	-1%	-4%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-4%	-3%	0%	-8%
Rheumatology	$534	8%	4%	1%	13%
Thoracic Surgery	$352	-4%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-4%
TOTAL	**$92,979**	**0%**	**0%**	**0%**	**0%**

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3. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold and the additional performance threshold, as the critical factors affecting the distribution of payment adjustments. We ran two separate models with performance thresholds of 35 and 50 respectively (as an alternative to the proposed performance threshold of 45) to estimate the impact of a more moderate and a more aggressive increase in the performance threshold. A lower performance threshold would be a more gradual transition and could potentially allow more clinicians to meet or exceed the performance threshold. The lower performance threshold would lower the amount of budget neutral dollars to redistribute and increase the number of clinicians with a positive payment adjustment, but the scaling factor would be lower. In contrast, a more aggressive increase would likely lead to higher positive payment adjustments for clinicians that exceed the performance threshold because the budget neutral pool would be redistributed among fewer clinicians. We ran each of these models using the proposed additional performance threshold of 80. In the model with a performance threshold of 35, we estimate that $466 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 5.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 8.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with a performance threshold of 50, we estimate that $644 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 6.1 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 15.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. We proposed a performance threshold of 45 because we believe increasing the performance threshold to 45 points was not unreasonable or too steep, but rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. We refer readers to section III.K.3.e.(2) of this proposed rule for additional rationale on the selection of the performance threshold.

To evaluate the impact of modifying the additional performance threshold, we ran two models with additional performance thresholds of 75 and 85 as an alternative to the proposed 80 points. We ran each of these models using a performance threshold of 45. The benefit of the model with the additional performance threshold of 75 would maintain the additional performance threshold that was in year 3. In the model with the additional performance threshold of 75, we estimate that $586 million would be redistributed through budget neutrality, and there would be a maximum payment adjustment of 4.8 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 12.7 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with an additional performance threshold of 85, we estimate that $586 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 8.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance among those that submit data. Also, that 12.7 percent of MIPS eligible clinicians will receive a negative payment adjustment among those that submit data. We proposed the additional performance threshold at 80 points because we believe raising the additional performance threshold would incentivize continued improved performance while accounting for policy changes in the fourth year of the program. We refer readers to section III.K.3.e.(3) of this proposed rule for additional rationale on the selection of additional performance threshold.

G. Impact on Beneficiaries

1. Medicare PFS

There are a number of changes in this proposed rule that will have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, will have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

2. Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new

proposed measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment. Similarly, our proposals in section III.K.3.g.(2) of this rule will improve the caliber and value of QCDR measures.

H. Burden Reduction Estimates

1. Payment for E/M Services

In the CY 2019 PFS final rule, we finalized proposals that we made in response to comments received from RFIs released to the public under our Patients Over Paperwork Initiative. Specifically, we finalized proposals that focused on simplifying the medical documentation payment framework for office/outpatient E/M services and allowing greater flexibility on the components practitioners could choose to document when billing Medicare for office/outpatient E/M visits. In that rule we discussed the specific changes to documentation requirements and estimated significant reductions in the amount of time that practitioners would spend documenting office/outpatient E/M visits, furthering our goal of allowing practitioners more time spent with patients. As discussed earlier in section II.P. of this proposed rule, we are proposing to adopt the revised office/outpatient E/M code set. Our new proposals reflect our ongoing dialog with the practitioner community and take into account the significant revisions the AMA/CPT editorial panel has made to the guidelines for the office/outpatient E/M code set. We note that as part of its efforts to revise the guidelines, the AMA has also estimated a reduction in the amount of time practitioners would spend documenting office/outpatient E/M visits. The AMA asserts that its revisions to the office/outpatient E/M code set will accomplish similar, albeit greater burden reduction in comparison with CMS' approach, as finalized in the CY 2019 PFS final rule, and is more intuitive and in line with the current practice of medicine. We reviewed the AMA's estimates and acknowledge that overall the AMA's approach does result in burden reduction that are consistent with our broader goals discussed above. In comparison to our estimates of burden reduction, as discussed in the CY 2019 final rule, the AMA's estimates show less documentation burden to practitioners, the difference resulting from CMS' finalized policies that allow use of add-on codes to reflect additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits that the current E/M coding and visit levels do not fully recognize (FR 83 59638). The AMA estimates reflect assumptions that the time spent documenting appropriate application of the add-on codes may result in additional burden to practitioners. We disagree with this assumption. In addition to proposing to redefine and revalue HCPCS G code add-on GPC1X to be more understandable and easy to report for purposes of medical documentation and billing, and proposing to delete HCPCS G-code add-on GCG0X, we believe that while an initial setup period is expected for practices to establish workflows that incorporate appropriate use of the add-on code, practices should be able to automate the appropriate use of the add-on code in a short period of time. Even so, our proposal to adopt the AMA's revised office/outpatient E/M code set is consistent with our goal of burden reduction and aligns with the policy principles that underlay what we finalized in the CY 2019 PFS final rule. The AMA's estimates of burden reduction as related to office/outpatient E/M documentation and other materials pertinent to the AMA/CPT and AMA/RUCs recent efforts to revise the office/outpatient E/M code set are available at *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*.

2. Beneficiary Liability

Many proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2019 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.92, which means that in CY 2019, a beneficiary would be responsible for 20 percent of this amount, or $21.98. Based on this proposed rule, using the CY 2020 CF, the CY 2020 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures public use file, is $110.43, which means that, in CY 2020, the final beneficiary coinsurance for this service would be $22.09.

I. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $874.88 (8.0 hours × $109.36). Therefore, we estimated that the total cost of reviewing this regulation is $13,399,662 ($874.88 × 15,316 reviewers).

J. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 119 and 120 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2019 to CY 2020 based on the FY 2020 President's Budget baseline.

TABLE 119—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2020 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 120—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2020 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

K. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 403.902 is amended—
■ a. By adding in alphabetical order the definitions of ''Certified nurse midwife'', ''Certified registered nurse anesthetist'', and ''Clinical nurse specialist'';
■ b. By revising the definition of ''Covered recipient'';
■ c. By adding in alphabetical order the definitions of ''Device identifier'', ''Long term medical supply or device loan'', ''Non-teaching hospital covered recipient'', ''Nurse practitioner'', ''Physician assistant'', ''Short term medical supply or device loan'', and ''Unique device identifier''.

The additions and revisions read as follows:

§ 403.902 Definitions.

* * * * *

Certified nurse midwife means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Certified registered nurse anesthetist means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

* * * * *

Clinical nurse specialist means, an individual who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(2) Holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

* * * * *

Covered recipient means—

(1) Any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment; or

Device identifier is the mandatory, fixed portion of a unique device identifier (UDI) that identifies the specific version or model of a device and the labeler of that device (as described at 21 CFR 801.3 in paragraph (1) of the definition of ''Unique device identifier'').

* * * * *

Long term medical supply or device loan means the loan of supplies or a device for 91 days or longer.

Non-teaching hospital covered recipient means a person who is one or more of the following: Physician, physician assistant, nurse practitioner, clinical nurse specialist, certified

registered nurse anesthetist, or certified nurse-midwife.

* * * * *

Nurse practitioner means a nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

* * * * *

Physician assistant means a physician assistant who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

* * * * *

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

* * * * *

Unique device identifier means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830.20 (mirrored from 21 CFR 801.3).

■ 3. Section 403.904 is amended by:

■ a. Revising paragraphs (c)(1), (c)(3) introductory text, (c)(3)(ii) and (iii), (c)(8), (e)(2) introductory text, (e)(2)(xiv);

■ b. Adding paragraph (e)(2)(xi);

■ c. Revising paragraph (e)(2)(xv);

■ d. Adding paragraph (e)(2)(xviii); and

■ e. Revising paragraphs (f)(1) introductory text, (f)(1)(i)(A) introductory text, (f)(1)(i)(A)(*1*), (f)(1)(i)(A)(*3*), (f)(1)(i)(A)(5), (f)(1)(iv), (f)(1)(v), (h)(5), (h)(7), and (h)(13).

The revisions and addition read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

* * * * *

(c) * * *

(1) *Name of the covered recipient.* For non-teaching hospital covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (NPPES) (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

* * * * *

(3) *Identifiers for non-teaching hospital covered recipients.* In the case of a covered recipient the following identifiers:

* * * * *

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a non-teaching hospital covered recipient, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license), and the State(s) in which the license is held.

* * * * *

(8) *Related covered drug, device, biological or medical supply.* Report the marketed or brand name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals—

(A) If the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(B) Any regularly used identifiers must be reported, including, but not limited to, national drug codes.

(ii) For devices, if the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable.

(iii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iv) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(v) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

* * * * *

(e) * * *

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xviii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

* * * * *

(xi) Debt forgiveness.

* * * * *

(xiv) Compensation for serving as faculty or as a speaker for a medical education program.

(xv) Long term medical supply or device loan.

* * * * *

(xviii) Acquisitions.

* * * * *

(f) * * *

(1) Research-related payments or other transfers of value to covered recipients, including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) * * *

(A) If paid to a non-teaching hospital covered recipient, all of the following must be provided:

(*1*) The non-teaching hospital covered recipient's name as listed in the NPPES (if applicable).

* * * * *

(*3*) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license) and State(s) in which the license is held.

* * * * *

(*5*) Primary business address of the non-teaching hospital covered recipient(s).

* * * * *

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section); for drugs and biologicals, the relevant National Drug Code(s), if any; and for devices and medical supplies, the relevant device identifier, if any, and the therapeutic area or product category if a marketed name is not available.

(v) Information about each non-teaching hospital covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

* * * * *

(h) * * *

(5) Short term medical supply or device loan.

* * * * *

(7) A transfer of anything of value to a non-teaching hospital covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

* * * * *

(13) In the case of a non-teaching hospital covered recipient, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

* * * * *

■ 4. Section 403.908 is amended by revising paragraphs (g)(2)(ii) introductory text to read as follows:

§ 403.908 Procedures for electronic submission of reports.

* * * * *

(g) * * *

(2) * * *

(ii) Covered recipients—

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.20 is amended by adding paragraph (e) to read as follows:

§ 410.20 Physicians' services.

* * * * *

(e) *Medical record documentation.* The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

■ 7. Section 410.40 is amended—

■ a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively;

■ b. By adding new paragraph (a);

■ c. In newly redesignated paragraph (b)(1) by removing the reference ''paragraphs (d) and (e)'' and adding in its place the reference ''paragraphs (e) and (f)''; and

■ d. By revising newly redesignated paragraphs (e)(2)(i), (e)(3)(i), and (e)(3)(iii) through (e)(3)(v).

The additions and revision reads as follows:

§ 410.40 Coverage of ambulance services.

(a) *Definitions.* As used in this section, the following definitions apply:

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

(A) Physician assistant (PA).

(B) Nurse practitioner (NP).

(C) Clinical nurse specialist (CNS).

(D) Registered nurse (RN).

(E) Licensed practical nurse (LPN).

(F) Social worker.

(G) Case manager.

(H) Discharge planner.

Physician certification statement means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

* * * * *

(e) * * *

(2) * * *

(i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

* * * * *

(3) * * *

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport, certifying that the medical necessity requirements of paragraph (e)(1) of this section are met.

* * * * *

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, or non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

* * * * *

■ 8. Section 410.41 is amended by revising the section heading and paragraph (c)(1) to read as follows:

§ 410.41 Requirements for ambulance providers and suppliers.

* * * * *

(c) * * *

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification is on file, if required.

* * * * *

■ 9. Section 410.49 is amended by revising paragraph (b)(1)(vii) and adding paragraph (b)(1)(viii) to read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

* * * * *

(b) * * *

(1) * * *

(vii) Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy

for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or

(viii) Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

* * * * *

■ 10. Section 410.59 is amended by—

■ a. Adding paragraphs (a)(4) and (e)(1)(v); and

■ b. Revising paragraphs (e)(2) introductory text, (e)(2)(i) and (v), and (e)(3).

The additions and revisions read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) Effective for dates of service on and after January 1, 2020, for occupational therapy services described in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by an occupational therapy assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the occupational therapy assistant either:

(A) Furnishes all the minutes of a service exclusive of the occupational therapist; or

(B) Furnishes a portion of a service—either concurrently with or separately from the part furnished by the occupational therapist—such that the minutes for that portion of a service furnished by the occupational therapy assistant exceed 10 percent of the total minutes for that service.

* * * * *

(e) * * *

(1) * * *

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is no longer applied as a limitation on incurred expenses for outpatient occupational therapy services, but, is instead applied as a threshold above which claims for occupational therapy services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient occupational therapy includes:

(i) Outpatient occupational therapy services furnished under this section;

* * * * *

(v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished under section 1834(k)(1)(B) of the Act.

* * * * *

(3) A process for medical review of claims for outpatient occupational therapy services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process applies when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 in 2027) by the increase in the Medicare Economic Index for the current year.

■ 11. Section 410.60 is amended by—

■ a. Adding paragraphs (a)(4) and (e)(1)(v); and

■ b. Revising paragraphs (e)(2) introductory text, (e)(2)(i), (ii) and (vi), and (e)(3).

The additions and revisions read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) Effective for dates of service on and after January 1, 2020, for physical therapy services described in paragraph (a)(3)(i) or (a)(3)(ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by a physical therapist assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant either:

(A) Furnishes all the minutes of a service exclusive of the physical therapist; or

(B) Furnishes a portion of a service either concurrently with or separately from the part furnished by the physical therapist such that the minutes for that portion of a service furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service.

* * * * *

(e) * * *

(1) * * *

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is not applied as a limitation on incurred expenses for outpatient physical therapy and outpatient speech-language pathology services, but is instead applied as a threshold above which claims for physical therapy and speech-language pathology services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record; and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient physical therapy includes:

(i) Outpatient physical therapy services furnished under this section;

(ii) Outpatient speech-language pathology services furnished under § 410.62;

* * * * *

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished and paid under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for physical therapy and speech-language pathology services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at

or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 for 2017) by the increase in the Medicare Economic Index for the current year.

■ 12. Section 410.67 is added to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

(a) *Basis and scope*—(1) *Basis.* This section implements sections 1861(jjj), 1861(s)(2)(HH), 1833(a)(1)(CC) and 1834(w) of the Act which provide for coverage of opioid use disorder treatment services furnished by an opioid treatment program and the payment of a bundled payment under part B to an opioid treatment program for opioid use disorder treatment services that are furnished to a beneficiary during an episode of care beginning on or after January 1, 2020.

(2) *Scope.* This section sets forth the criteria for an opioid treatment program, the scope of opioid use disorder treatment services, and the methodology for determining the bundled payments to opioid treatment programs for furnishing opioid use disorder treatment services.

(b) *Definitions.* For purposes of this section, the following definitions apply:

Episode of care means a one week (contiguous 7-day) period.

Opioid treatment program means an entity that is an opioid treatment program (as defined in § 8.2 of this title, or any successor regulation) that meets the requirements described in paragraph (c) of this section.

Opioid use disorder treatment service means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid treatment program that meets the requirements described in paragraph (c) of this section.

(1) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

(2) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

(4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

(5) Toxicology testing.

Partial episode of care means an episode of care in which at least one opioid use disorder treatment service, but less than a majority of the opioid use disorder treatment services identified in the patient's current treatment plan (including any changes noted in the patient's medical record), is furnished.

(c) *Requirements for opioid treatment programs.* To participate in the Medicare program and receive payment, an opioid treatment program must meet all of the following:

(1) Be enrolled in the Medicare program.

(2) Have in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opioid treatment program.

(3) Be accredited by an accrediting body approved by the SAMHSA.

(4) Have in effect a provider agreement under part 489 of this title.

(d) *Bundled payments for opioid use disorder treatment services furnished by opioid treatment programs.*

(1) CMS will establish categories of bundled payments for opioid treatment programs as follows:

(i) Categories for each type of opioid agonist and antagonist treatment medication;

(ii) A category for medication not otherwise specified, which must be used for new FDA-approved opioid agonist or antagonist treatment medications for which CMS has not established a category; and

(iii) A category for no medication provided. Each category of bundled payment must consist of a payment amount for a full episode of care and a payment amount for a partial episode of care.

(2) The bundled payment for episodes of care in which a medication is provided must consist of payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other opioid use disorder treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component must be added together to create the bundled payment amount. The bundled payment for episodes of care in which no medication is provided shall consist of a single payment amount for all opioid use disorder treatment services reflected in the patient's treatment plan (not including medication or dispensing/administration of such medication).

(i) *Drug component for full episodes of care.* For full episodes of care, the payment for the drug component will be determined as follows, using the most recent data available at time of ratesetting for the applicable calendar year:

(A) For implantable and injectable medications, the payment must be determined using the methodology set forth in section 1847A of the Act, except that the payment amount shall be 100 percent of the ASP if ASP is used.

(B) For oral medications, the payment amount must be 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart 800 of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount must be based on an alternative methodology as determined by the Secretary.

(C) *Exception.* For the drug component of bundled payments in the medication not otherwise specified category under paragraph (d)(1)(B) of this section, the payment amount must be based on the applicable methodology under paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) of this section (applying the most recent available data for such new medication), or invoice pricing until the necessary data become available.

(ii) *Drug component for partial episodes of care.* For partial episodes of care, the payment for the drug

component will be determined as follows:

(A) For oral medications, the amount will be half of the payment amount for the full episode of care.

(B) For injectable and implantable medications, the amount will be the same as the payment amount for the full episode of care.

(iii) *Non-drug component for full episodes of care.* For full episodes of care, the payment for CY 2020 for the non-drug components of the bundled payments will be based on the CY 2019 TRICARE weekly bundled rate for items and services furnished when a patient is prescribed methadone, minus the methadone cost, and adjusted as follows:

(A) For oral medications, no further adjustment.

(B) For injectable medications, to subtract an amount reflecting the cost of dispensing methadone and to add an amount reflecting the CY 2019 non-facility Medicare payment rate for the administration of an injection.

(C) For implantable medications, to subtract an amount reflecting the cost of dispensing methadone and to add an amount reflecting the CY 2019 non-facility Medicare payment rate for insertion, removal, or insertion and removal of the implant, as applicable.

(iv) *Non-drug component for partial episodes of care.* For partial episodes of care, the payment for CY 2020 for the non-drug components of the bundled payments will be based on the CY 2019 TRICARE weekly bundled rate for items and services furnished when a patient is prescribed methadone, minus the methadone cost, adjusted as follows:

(A) For oral medications, to halve the amount.

(B) For injectable medications, to subtract an amount reflecting the cost of dispensing methadone and then to halve the remaining amount. The resulting amount will be added to an amount reflecting the CY 2019 non-facility Medicare payment rate for the administration of an injection.

(C) For implantable medications, to subtract an amount reflecting the cost of dispensing methadone and then to halve the remaining amount. The resulting amount will be added to an amount reflecting the CY 2019 non-facility Medicare payment rate for insertion, removal, or insertion and removal of the implant, as applicable.

(v) *No medication provided, full and partial episodes of care.* The bundled payment amount for CY 2020 for a full episode of care in which no medication is provided will be based on the CY 2019 TRICARE weekly bundled rate for items and services furnished when a patient is prescribed methadone, minus the methadone cost, and minus an amount reflecting the cost of dispensing methadone. The bundled payment amount for CY 2020 for a partial episode of care in which no medication is provided will be half the payment amount for a full episode of care in which no medication is provided.

(3) Adjustments will be made to the bundled payment for the following:

(i) If the opioid treatment program furnishes counseling or therapy services in excess of the amount specified in the beneficiary's treatment plan and for which medical necessity is documented in the medical record, an adjustment will be made for each additional 30 minutes of counseling or individual therapy furnished during the episode of care or partial episode of care.

(ii) The payment amount for the non-drug component and the full bundled payment for an episode of care or partial episode of care in which no medication is provided will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26.

(iii) The payment amount for the non-drug component and the full bundled payment for an episode of care or partial episode of care in which no medication is provided will be updated annually using the Medicare Economic Index described in § 405.504(d).

(4) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment must be considered a duplicative payment if delivery, administration or dispensing of the same medications was also separately paid under Medicare Parts B or D. CMS will recoup the duplicative payment made to the opioid treatment program.

(e) *Beneficiary cost-sharing.* A beneficiary copayment amount of zero will apply.

■ 13. Section 410.74 is amended by revising paragraph (a)(2)(iv), and adding paragraph (e) to read as follows:

§ 410.74 Physician assistants' services.

(a) * * *

(2) * * *

(iv) Performs the services in accordance with State law and State scope of practice rules for PAs in the State in which the physician assistant's professional services are furnished, with medical direction and appropriate supervision as provided by State law in which the services are performed. In the absence of State law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their professional services.

* * * * *

(e) *Medical record documentation.* For physician assistants' services, the physician assistant may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the physician assistant's presence and participation in the service.

■ 14. Section 410.75 is amended by adding paragraph (f) to read as follows:

§ 410.75 Nurse practitioners' services.

* * * * *

(f) *Medical record documentation.* For nurse practitioners' services, the nurse practitioner may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the nurse practitioner's presence and participation in the service.

■ 15. Section 410.76 is amended by adding paragraph (f) to read as follows:

§ 410.76 Clinical nurse specialists' services.

* * * * *

(f) *Medical record documentation.* For clinical nurse specialists' services, the clinical nurse specialist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the clinical nurse specialist's presence and participation in the service.

■ 16. Section 410.77 is amended by adding paragraph (e) to read as follows:

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

* * * * *

(e) *Medical record documentation.* For certified nurse-midwives' services, the certified nurse-midwife may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians, residents, nurses, students, or other members of the medical team, including, as applicable, notes documenting the certified nurse-midwife's presence and participation in the service.

■ 17. Section 410.105 is amended by adding paragraph (d) to read as follows:

§ 410.105 Requirements for coverage of CORF services.

* * * * *

(d) *Claims.* Effective for dates of service on and after January 1, 2020 physical therapy or occupational therapy services covered as part of a rehabilitation plan of treatment described in paragraph (c) of this section, as applicable—

(1) Claims for such services furnished in whole or in part by a physical therapist assistant or an occupational therapy assistant must be identified with the inclusion of the respective prescribed modifier; and

(2) Effective for dates of service on and after January 1, 2022, such claims are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service as defined at section 1834(k) of the Act.

(3) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant or occupational therapy assistant either—

(i) Furnishes all the minutes of a service exclusive of the respective physical therapist or occupational therapist; or

(ii) Furnishes a portion of a service—either concurrently with or separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service exceed 10 percent of the total time for that service.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 18. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 19. Section 411.370 is amended—

■ a. In paragraph (b) introductory text, by removing the phrase ''CMS determines'' and adding in its place the phrase ''CMS will determine''; and

■ b. By revising paragraphs (b)(1), (c) introductory text, (d), and (e).

The revisions read as follows:

§ 411.370 Advisory opinions relating to physician referrals.

* * * * *

(b) * * *

(1) The request must relate to an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. Requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties are not appropriate for an advisory opinion.

* * * * *

(c) *Matters not subject to advisory opinions.* CMS will not address through an advisory opinion—

* * * * *

(d) *Facts subject to advisory opinions.* The requestor must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Acceptance of requests.* (1) CMS does not accept an advisory opinion request or issue an advisory opinion if —

(i) The request is not related to a named individual or entity;

(ii) The request does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information;

(iii) CMS is aware, after consultation with OIG and DOJ, that the same course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(iv) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(2) CMS may elect not to accept an advisory opinion request if it determines, after consultation with OIG and DOJ, that the course of action described is substantially similar to a course of conduct that is under investigation or is the subject of a proceeding involving the Department or other law enforcement agencies, and issuing an advisory opinion could interfere with the investigation or proceeding.

* * * * *

■ 20. Section 411.372 is amended by revising paragraphs (b)(4)(i) and (ii), (5), (6), and (8)(ii) to read as follows:

§ 411.372 Procedure for submitting a request.

* * * * *

(b) * * *

(4) * * *

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including:

(A) The purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved); and

(B) Any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal service or employment contracts, leases, deeds, pension or insurance plans, or financial statements (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

* * * * *

(5) The identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.354), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions to be addressed by CMS including, if possible, a discussion of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

* * * * *

(8) * * *

(ii) The chief executive officer, or other authorized officer, of the requestor, if the requestor is a corporation;

* * * * *

■ 21. Section 411.375 is amended by revising paragraphs (a) and (b) to read as follows:

§ 411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion a check or money order payable to CMS for $250. This initial payment is nonrefundable.

(b) *How costs are calculated.* In addition to the initial payment, CMS will charge an hourly rate of $220. Parties may request an estimate from CMS after submitting a complete request. Before issuing the advisory opinion, CMS calculates the fee for responding to the request.

* * * * *

§ 411.379 [Amended]

■ 22. Section 411.379(e) is amended by removing the phrase ''The 90-day period'' and adding in its place the phrase ''The 60-day period''.

§ 411.380 [Amended]

■ 23. Section 411.380 is amended—

■ a. In paragraph (c)(1), by removing the phrase ''within 90 days'' and adding in its place the phrase ''within 60 days''.

■ b. In paragraph (c)(2), by removing the phrase ''If the 90th day'' and adding in its place the phrase ''If the 60th day''.

■ c. In paragraph (c)(3) introductory text, by removing the phrase ''The 90-day period'' and adding in its place the phrase ''The 60-day period''.

§ 411.384 [Amended]

■ 24. Section 411.384(b) is amended by removing the phrase ''for public inspection during its normal hours of operation and''.

■ 25. Section 411.387 is revised to read as follows:

§ 411.387 Effect of an advisory opinion.

(a) An advisory opinion is binding on the Secretary, and a favorable advisory opinion shall preclude imposition of sanctions under section 1877(g) of the Act with respect to:

(1) The individuals or entities requesting the opinion; and

(2) Individuals or entities that are parties to the specific arrangement with respect to which such advisory opinion has been issued.

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 26. The authority for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

§ 414.601 [Amended]

■ 27. Section 41.601 is amended by adding the sentence ''Section 1834(l)(17) of the Act requires the development of a data collection system to collect cost, revenue, utilization, and other information determined appropriate from providers of services and suppliers of ground ambulance services.'' to to the end of the section.

■ 28. Section 414.605 is amended by adding the definition of ''ground ambulance organization'' in alphabetical order to read as follows:

§ 414.605 Definitions.

* * * * *

Ground ambulance organization means a Medicare provider or supplier of ground ambulance services.

* * * * *

■ 29. Section 414.610 is amended by adding paragraph (c)(9) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(9) *Payment Reduction for Failure to Report Data.* In the case of a ground ambulance organization (as defined at § 414.605) that is selected by CMS under § 414.626(c) for a year that does not sufficiently submit data under § 414.626(b) and is not granted a hardship exemption under § 414.626(d), the payments made under this section are reduced by 10 percent for the applicable period. For purposes of this paragraph, the applicable period is the calendar year that begins following the date that CMS provided written notification to the ground ambulance organization under § 414.626(e)(1) that the ground ambulance did not sufficiently submit the required data.

* * * * *

■ 30. Section 414.626 is added to read as follows:

§ 414.626 Data reporting by ground ambulance organizations.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Data collection period means, with respect to a year, the 12-month period that reflects the ground ambulance organization's annual accounting period.

Data reporting period means, with respect to a year, the 5 month period that begins the day after the last day of the ground ambulance organization's data collection period.

For a year means one of the calendar years from 2020 through 2024.

(b) *Data collection and submission requirement.* Except as provided in paragraph (d) of this section, a ground ambulance organization selected by CMS under paragraph (c) of this section must do the following:

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to the ambulance organization's Medicare Administrative Contractor in accordance with CMS instructions on reporting the data collection period.

(2) Collect during its selected data collection period the data necessary to complete the Medicare Ground Ambulance Data Collection Instrument.

(3) Submit to CMS a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to the ground ambulance organization's selected data collection period.

(c) *Representative sample.* (1) *Random sample.* For purposes of the data collection described in paragraph (b) of this section, and for a year, CMS will select a random sample of 25 percent of eligible ground ambulance organizations that is stratified based on:

(i) Provider versus supplier status, ownership (for-profit, non-profit, and government);

(ii) Service area population density (transports originating in primarily urban, rural, and super rural zip codes); and

(iii) Medicare-billed transport volume categories.

(2) *Selection eligibility.* A ground ambulance organization is eligible to be selected for data reporting under this section for a year if it is enrolled in Medicare and has submitted to CMS at least one Medicare ambulance transport claim during the year prior to the selection under paragraph (b)(1) of this section.

(3) *Notification of selection for a year.* CMS will notify an eligible ground ambulance organization that it has been selected to report data under this section for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data

by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

(4) *Limitation.* CMS will not select the same ground ambulance organization under this paragraph (c) in 2 consecutive years, to the extent practicable.

(d) *Hardship exemption.* A ground ambulance organization selected under paragraph (c) of this section may request and CMS may grant an exception to the reporting requirements under paragraph (b) of this section in the event of a significant hardship such as, a natural disaster, bankruptcy, or similar situation that the Secretary determines interfered with the ability of the ground ambulance organization to submit such information in a timely manner for the data collection period selected by the ground ambulance organization.

(1) To request a hardship exemption, the ground ambulance organization must submit a request form (accessed on the Ambulances Services Center website (*https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*) to CMS within 90 calendar days of the date that CMS notified the ground ambulance organization that it would receive a 10 percent payment reduction as a result of not submitting sufficient information under the data collection system. The request form must include all of the following:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Ground ambulance organization address.

(iv) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address (must include a physical address, a post office box address is not acceptable).

(v) Reason for requesting a hardship exemption.

(vi) Evidence of the impact of the hardship (such as photographs, newspaper or other media articles, financial data, bankruptcy filing, etc.).

(vii) Date when the ground ambulance organization would be able to begin collecting data under paragraph (b) of this section.

(viii) Date and signature of the chief executive officer or other designated personnel of the ground ambulance organization.

(2) CMS will provide a written response to the hardship exemption request within 30 days of its receipt of the hardship exemption form.

(e) *Notification of non-compliance and informal review.* (1) *Notification of non-compliance.* A ground ambulance organization selected under paragraph (c) of this section for a year that does not sufficiently report data under paragraph (b) of this section, and that is not granted a hardship exemption under paragraph (d) of this section, will receive written notification from CMS that it will receive a payment reduction under § 414.610(c)(9).

(2) *Informal review.* A ground ambulance organization that receives a written notification under paragraph (e)(1) of a payment reduction under § 414.610(c)(9) may submit a request for an informal review within 90 days of the date it received the notification by submitting all of the following information:

(i) Ground ambulance organization name.

(ii) NPI number.

(iii) Chief executive officer and any other designated personnel contact information, including name, email address, telephone number and mailing address with the street location of the ground ambulance organization.

(iv) Ground ambulance organization's selected data collection period and data reporting period.

(v) A statement of the reasons why the ground ambulance organization does not agree with CMS's determination and any supporting documentation.

(f) *Public availability of data.* Beginning in 2022, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

(g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

■ 31. Section 414.1305 is amended by—

■ a. Adding the definition of ''Aligned Other Payer Medical Home Model'' in alphabetical order;

■ b. Revising the definition of ''Hospital-based MIPS eligible clinician'';

■ c. Adding the definition of ''MIPS Value Pathway'' in alphabetical order; and

■ d. Revising the definition of ''Rural area''.

The additions and revision read as follows:

§ 414.1305 Definitions.

* * * * *

Aligned Other Payer Medical Home Model means an aligned other payer payment arrangement (not including a Medicaid payment arrangement) operated by a payer formally partnering in a CMS Multi-Payer Model that is a Medical Home Model through a written expression of alignment and cooperation, such as a memorandum of understanding (MOU) with CMS, and is determined by CMS to have the following characteristics:

(1) The other payer payment arrangement has a primary care focus with participants that primarily include primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services. For the purposes of this provision, primary care focus means the inclusion of specific design elements related to eligible clinicians practicing under one or more of the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant;

(2) Empanelment of each patient to a primary clinician; and

(3) At least four of the following:

(i) Planned coordination of chronic and preventive care.

(ii) Patient access and continuity of care.

(iii) Risk-stratified care management.

(iv) Coordination of care across the medical neighborhood.

(v) Patient and caregiver engagement.

(vi) Shared decision-making.

(vii) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings or population-based payments).

* * * * *

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) For the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus

outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period; and

(3) Beginning with the 2022 MIPS payment year, an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period.

* * * * *

MIPS Value Pathway means a subset of measures and activities specified by CMS.

* * * * *

Rural area means a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available.

* * * * *

■ 32. Section 414.1310 is amended by—

■ a. Revising paragraph (e)(2)(ii); and

■ b. Removing paragraphs (e)(3) through (5);

The revision reads as follows:

§ 414.1310 Applicability.

* * * * *

(e) * * *

(2) * * *

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the group's TIN for whom the group has data in CEHRT.

* * * * *

■ 33. Section 414.1315 is amended by revising paragraph (d)(2) to read as follows:

§ 414.1315 Virtual groups.

* * * * *

(d) * * *

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs, and for the Promoting Interoperability performance category, must aggregate the performance data of all of the MIPS eligible clinicians in the virtual group's TINs for whom the virtual group has data in CEHRT.

* * * * *

■ 34. Section 414.1320 is amended by adding paragraph (f) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(f) For purposes of the 2023 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 35. Section 414.1330 is amended by adding paragraphs (b)(4), (5), and (6) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(4) 40 percent of a MIPS eligible clinician's final score for MIPS payment year 2022.

(5) 35 percent of a MIPS eligible clinician's final score for MIPS payment year 2023.

(6) 30 percent of a MIPS eligible clinician's final score for MIPS payment year 2024 and future years.

■ 36. Section 414.1335 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(3) * * *

(i) For the 12-month performance period, a group that participates in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

* * * * *

■ 37. Section 414.1340 is amended by adding paragraph (d) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

* * * * *

(d) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 38. Section 414.1350 is amended by—

■ a. Revising paragraphs (b) and (c)(2); and

■ b. Adding paragraphs (d)(4), (5), and (6).

The revisions and additions read as follows:

§ 414.1350 Cost performance category.

* * * * *

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level for the 2017 thorough 2019 performance periods.

(2) For the total per capita cost measure specified for the 2017 through 2019 performance periods, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary clinician (MSPB clinician) measure specified for the 2017 through 2019 performance periods, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB clinician measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E&M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified for the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(8) Beginning with the 2020 performance period, each cost measure is attributed according to the measure specifications for the applicable performance period.

* * * * *

(c) * * *

(2) For the Medicare spending per beneficiary clinician measure, the case minimum is 35.

* * * * *

(d) * * *

(4) 20 percent of a MIPS eligible clinician's final score for MIPS payment year 2022.

(5) 25 percent of a MIPS eligible clinician's final score for MIPS payment year 2023.

(6) 30 percent of a MIPS eligible clinician's final score for MIPS payment year 2024 and each subsequent MIPS payment year.

■ 39. Section 414.1360 is amended by adding paragraph (a)(2) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(2) *Groups and virtual groups.* Beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, and the NPIs must perform the same activity for the same continuous 90 days in the performance period.

* * * * *

■ 40. Section 414.1370 is amended by amending paragraph (e)(2) to read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(e) * * *

(2) For purposes of calculating the APM Entity group score under the APM scoring standard, MIPS scores submitted by virtual groups will not be included.

* * * * *

■ 41. Section 414.1380 is amended—

■ a. In paragraph (b)(1)(i) introductory text by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ b. In paragraph (b)(1)(i)(A)(*1*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ c. By revising paragraph (b)(1)(ii) introductory text;

■ d. By adding paragraph (b)(1)(ii)(C);

■ e. By revising paragraph (b)(1)(v)(A)(*1*)(*i*);

■ f. In paragraph (b)(1)(v)(A)(*1*)(*ii*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ g. In paragraph (b)(1)(v)(B)(*1*)(*i*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019 through 2022'';

■ h. In paragraph (b)(1)(vi)(C)(*4*) by removing the phrase ''2020 and 2021 MIPS payment year'' and adding in its place the phrase ''2020 through 2022 MIPS payment years'';

■ i. By revising paragraph (b)(3)(ii)(A) and (C);

■ j. In paragraph (c)(2)(i)(A)(*4*) by removing the phrase ''beginning with the 2021 MIPS payment year'' and adding in its place the phrase ''for the 2021 and 2022 MIPS payment years'';

■ k. In paragraph (c)(2)(i)(A)(*5*) by removing the years ''2019, 2020, and 2021'' and adding in its place the years ''2019, 2020, 2021, and 2022'';

■ l. By adding paragraph (c)(2)(i)(A)(*9*);

■ m. By revising paragraph (c)(2)(i)(C) introductory text;

■ n. By adding paragraphs (c)(2)(i)(C)(*10*) and (c)(2)(ii)(D), (E), and (F);

■ o. By revising paragraph (c)(2)(iii) and (c)(3) introductory text; and

■ p. In paragraph (e)(2)(i)(C) by removing the phrase ''Can be attributed'' and adding in its place the phrase ''Can be assigned''.

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) *Benchmarks.* Except as provided in paragraphs (b)(1)(ii)(B) and (C) of this section, benchmarks will be based on performance by collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

* * * * *

(C) Beginning with the 2022 MIPS payment year, for each measure that has a benchmark that CMS determines may have the potential to result in inappropriate treatment, CMS will set benchmarks using a flat percentage for all collection types where the top decile is higher than 90 percent under the methodology at paragraph (b)(1)(ii) of this section.

* * * * *

(v) * * *

(A) * * *

(*1*) * * *

(*i*) Each high priority measure must meet the case minimum requirement at paragraph (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

* * * * *

(3) * * *

(ii) * * *

(A) The practice has received accreditation from an accreditation organization that is nationally recognized.

* * * * *

(C) The practice is a comparable specialty practice that has received recognition through a specialty recognition program offered through a nationally recognized accreditation organization; or

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*9*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

* * * * *

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. Except as provided in paragraph (c)(2)(i)(C)(10) of this section, in the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(10) Beginning with the 2020 MIPS payment year, CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the clinician and its agents.

* * * * *

(ii) * * *

(D) For the 2022 MIPS payment year:

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Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40	20	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	65	20	15	0
No Quality	0	20	15	65
No Improvement Activities	55	20	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	85	15	0
No Promoting Interoperability and no Improvement Activities	80	20	0	0
No Quality and no Improvement Activities	0	20	0	80

(E) For the 2023 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	35	25	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	50	35	15	0
No Quality	0	40	15	45
No Improvement Activities	45	30	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	65	0	0	35
No Promoting Interoperability and no Quality	0	85	15	0
No Promoting Interoperability and no Improvement Activities	55	45	0	0
No Quality and no Improvement Activities	0	45	0	55

(F) For the 2024 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
Reweight One Performance Category:				
No Cost	55	0	15	30
No Promoting Interoperability	45	40	15	0
No Quality	0	45	15	40
No Improvement Activities	40	35	0	25
Reweight Two Performance Categories:				
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	60	0	0	40
No Promoting Interoperability and no Quality	0	85	15	0
No Promoting Interoperability and no Improvement Activities	50	50	0	0
No Quality and no Improvement Activities	0	60	0	40

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(iii) For the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section, or the group or virtual group must meet the definition of a hospital-based MIPS eligible clinician or a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(3) *Complex patient bonus.* For the 2020, 2021 and 2022 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

* * * * *

■ 42. Section 414.1385 is amended by revising paragraph (a) to read as follows:

§ 414.1385 Targeted review and review limitations.

(a) *Targeted review.* A MIPS eligible clinician or group may request a targeted review of the calculation of the MIPS payment adjustment factor under section 1848(q)(6)(A) of the Act and, as applicable, the calculation of the additional MIPS payment adjustment factor under section 1848(q)(6)(C) of the Act (collectively referred to as the MIPS payment adjustment factors) applicable to such MIPS eligible clinician or group for a year. The process for targeted review is as follows:

(1) A MIPS eligible clinician or group (including their designated support staff), or a third party intermediary as defined at § 414.1305, may submit a request for a targeted review.

(2) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year. The targeted review request submission period may be extended as specified by CMS.

(3) A request for a targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside of the scope of the targeted review, which is limited to the calculation of the MIPS payment adjustment factors applicable to the MIPS eligible clinician or group for a year. If the targeted review request is denied, there will be no change to the MIPS final score or associated MIPS payment adjustment factors for the MIPS eligible clinician or group. If the targeted review request is approved, the MIPS final score and associated MIPS payment adjustment factors may be revised, if applicable, for the MIPS eligible clinician or group.

(4) CMS will respond to each request for a targeted review timely submitted and determine whether a targeted review is warranted.

(5) A request for a targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from the MIPS eligible clinician or group that is the subject of a request for a targeted review, it must be provided and received by CMS within 30 days of CMS's request. Non-responsiveness to CMS's request for additional information may result in a final decision based on the information available, although another request for a targeted review may be submitted before the end of the targeted review request submission period.

(6) If a request for a targeted review is approved, CMS may recalculate, to the extent feasible and applicable, the scores of a MIPS eligible clinician or group with regard to measures, activities, performance categories, and the final score, as well as the MIPS payment adjustment factors.

(7) Decisions based on the targeted review are final, and there is no further review or appeal. CMS will notify the individual or entity that submitted the request for a targeted review of the final decision.

(8) Documentation submitted for a targeted review must be retained by the submitter for 6 years from the end of the MIPS performance period.

* * * * *

■ 43. Section 414.1395 is amended by revising paragraph (a) to read as follows:

§ 414.1395 Public reporting.

(a) *General.* (1) CMS posts on Physician Compare, in an easily understandable format, the following:

(i) Information regarding the performance of MIPS eligible clinicians, including, but not limited to, final scores and performance category scores for each MIPS eligible clinician; and

(ii) The names of eligible clinicians in Advanced APMs and, to the extent feasible, the names and performance of such Advanced APMs.

(2) CMS periodically posts on Physician Compare aggregate

information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians with respect to each performance category.

(3) The information made available under this section will indicate, where appropriate, that publicized information may not be representative of an eligible clinician's entire patient population, the variety of services furnished by the eligible clinician, or the health conditions of individuals treated.

* * * * *

■ 44. Section 414.1400 is amended by—

■ a. Revising paragraphs (a)(2) introductory text and (a)(2)(iii);

■ b. Adding paragraphs (a)(4)(v) and (vi),

■ c. Revising paragraph (b)(1),

■ d. Adding paragraphs (b)(2)(iii) and (iv), (b)(3)(iv) through (vii), ;

■ e. Revising paragraph (c)(1);

■ f. Adding paragraphs (c)(2)(i) and (ii); and

■ g. Revising paragraphs (f)(1) introductory text and (f)(3) introductory text.

The revision and addition reads as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(2) Beginning with the 2021 performance period and all future years, for the following MIPS performance categories, QCDRs and qualified registries must be able to submit data for all categories, and Health IT vendors must be able to submit data for at least one category:

* * * * *

(iii) Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*)).

* * * * *

(4) * * *

(v) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(vi) Prior to discontinuing services to any MIPS eligible clinician, group, or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate data submission mechanism or third party intermediary according to a CMS approved a transition plan.

* * * * *

(b) * * *

(1) *QCDR self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a QCDR must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. Beginning with the 2023 payment year, QCDRs are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at paragraph (b)(2)(iv) of this section), and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Each QCDR would still be required to submit notification to CMS within the reporting period promptly within the month of realization of the impending deficiency in order to be considered for this exception, as discussed at paragraph (b)(2)(iv) of this section.

(2) * * *

(iii) Beginning with the 2023 MIPS payment year, the QCDR must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives.

(iv) Beginning with the 2023 MIPS payment year, require QCDRs to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR. Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period.

* * * * *

(3) * * *

(iv) QCDR measure considerations for approval include:

(A) Preference for measures that are outcome-based rather than clinical process measures.

(B) Measures that address patient safety and adverse events.

(C) Measures that identify appropriate use of diagnosis and therapeutics.

(D) Measures that address the domain of care coordination.

(E) Measures that address the domain for patient and caregiver experience.

(F) Measures that address efficiency, cost, and resource use.

(G) Beginning with the 2021 performance period—

(*1*) That QCDRs link their QCDR measures to the following at the time of self-nomination:

(*i*) Cost measure,

(*ii*) Improvement activity,

(*iii*) An MVP.

(*2*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(H) Beginning with the 2020 performance period CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(I) QCDRs should conduct an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and utilize the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.

(J) Beginning with the 2020 performance period, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*1*) Beginning with the 2020 performance period, in instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure

participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*2*) [Reserved]

(v) QCDR measure requirements for approval include:

(A) QCDR Measures that are beyond the measure concept phase of development.

(B) QCDR Measures that address significant variation in performance.

(C) Beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

(D) Beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(E) Beginning with the 2020 performance period, areas of duplication identified by CMS should be addressed within a year of the request. If the QCDR measures are not harmonized, CMS may reject the duplicative QCDR measure.

(vi) Beginning with the 2021 performance period, QCDR measures may be approved for 2 years, at CMS discretion, by attaining approval status by meeting QCDR measure considerations and requirements, Upon annual review, CMS may revoke QCDR measure second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; requires QCDR measure harmonization; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(vii) Beginning with the 2020 performance period, QCDR measure rejection criteria considerations, that include, but are not limited to, the following factors:

(A) QCDR measures that are duplicative, or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) Whether the previously identified areas of duplication have been addressed as requested.

(I) QCDR measures that split a single clinical practice or action into several QCDR measures.

(J) QCDR measures that are ''check-box'' with no actionable quality action.

(K) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(L) Whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality actions, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.

(M) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(N) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(c) * * *

(1) *Qualified registry self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a qualified registry must self-nominate from September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period. Beginning with the 2023 payment year, qualified registries are required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year (as specified at § 414.1400(c)(2)(ii)), and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Each qualified registry would still be required to submit notification to CMS within the reporting period promptly within the month of realization of the impending deficiency in order to be considered for this exception, as discussed at § 414.1400(c)(2)(ii).

(2) * * *

(i) Beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) Beginning with the 2023 MIPS payment year, require qualified registries to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the qualified registries. Exceptions to this requirement may occur if the qualified registries does not receive the data from their clinician until the end of the performance period

* * * * *

(f) * * *

(1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(5) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

* * * * *

(3) For purposes of paragraph (f) of this section, CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, including but not limited to, if the submitted data:

* * * * *

■ 45. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(7) and (8);

■ b. Adding paragraph, (d)(6) and (7); and

■ c. Revising paragraph (f) introductory text.

The additions and revisions read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(7) The performance threshold for the 2022 MIPS payment year is 45 points.

(8) The performance threshold for the 2023 MIPS payment year is 60 points.

* * * * *

(d) * * *

(6) The additional performance threshold for the 2022 MIPS payment year is 80 points.

(7) The additional performance threshold for the 2023 MIPS payment year is 85 points.

* * * * *

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Beginning with the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

* * * * *

■ 46. Section 414.1415 is amended by revising paragraph (c)(5) and (6) to read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(c) * * *

(5) For the purposes of this section, expected expenditures means the beneficiary expenditures for which an APM Entity is responsible under an APM. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Advanced APM determinations, the expected expenditures under the terms of the APM should not exceed the Medicare Part A and B expenditures for a participant in the absence of the APM. If the expected expenditures under the APM exceed the Medicare Part A and B expenditures that an APM Entity would be expected to incur in the absence of the APM, such excess expenditures are not considered when CMS assesses financial risk under the APM for purposes of Advanced APM determinations.

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 CFR part 422) are not considered capitation arrangements for purposes of this paragraph (c)(6).

* * * * *

■ 47. Section 414.1420 is amended by revising paragraph (d)(2) introductory text, (d)(2)(ii), (d)(3)(ii)), (d)(4) introductory text, (d)(5), (6), (7) and (8) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(d) * * *

(2) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model financial risk standard.* The APM Entity participates in a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model that, based on the APM Entity's failure to meet or exceed one or more specified performance standards, does one or more of the following:

* * * * *

(ii) Require direct payment by the APM Entity to the payer;

* * * * *

(3) * * *

(ii) Except for risk arrangements described under paragraph (d)(2) of this section, the risk arrangement must have a marginal risk rate of at least 30 percent.

* * * * *

(4) *Medicaid Medical Home Model and Aligned Other Payer Medical Home Model nominal amount standard.* For a Medicaid Medical Home Model or an Aligned Other Payer Medical Home Model to meet the Medicaid Medical Home Model nominal amount standard, the total annual amount that an APM Entity potentially owes a payer or forgoes must be at least the following amounts:

* * * * *

(5) *Marginal risk rate.* For purposes of this section, the marginal risk rate is defined as the percentage of actual expenditures that exceed expected expenditures for which an APM Entity is responsible under an other payer payment arrangement.

(i) In the event that the marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the average marginal risk rate across all possible levels of actual expenditures would be used for comparison to the marginal risk rate specified in paragraph (d)(3)(ii) of this section, with exceptions for large losses as described in paragraph (d)(5)(ii) of this section and small losses as described in paragraph (d)(5)(iii) of this section.

(ii) *Allowance for large losses.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by an amount sufficient to require the APM Entity to make financial risk payments under the other payer payment arrangement greater than or equal to the total risk requirement under paragraph (d)(3)(i) of this section.

(iii) *Allowance for minimum loss rate.* The determination in paragraph (d)(3)(ii) of this section may disregard the marginal risk rates that apply in cases when actual expenditures exceed expected expenditures by less than 4 percent of expected expenditures.

(6) *Expected expenditures.* For the purposes of this section, expected expenditures is defined as the Other Payer APM benchmark. For episode payment models, expected expenditures means the episode target price. For purposes of assessing financial risk for Other Payer Advanced APM determinations, the expected expenditures under the payment arrangement should not exceed the expenditures for a participant in the absence of the payment arrangement. If expected expenditures (that is, benchmarks) under the payment arrangement exceed the expenditures that the participant would be expected to incur in the absence of the payment arrangement, such excess expenditures are not considered when assessing financial risk under the payment arrangement for Other Payer Advanced APM determinations.

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purposes of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 CFR part 422) are not considered capitation arrangements for purposes of this paragraph.

(8) *Aligned Other Payer Medical Home Model and Medicaid Medical Home Model 50 eligible clinician limit.* Notwithstanding paragraphs (d)(2) and (4) of this section, if an APM Entity

participating in an Aligned Other Payer Medical Home Model or Medicaid Medical Home Model is owned and operated by an organization with 50 or more eligible clinicians whose Medicare billing rights have been reassigned to the TIN(s) of the organization(s) or any of the organization's subsidiary entities, the requirements of paragraphs (d)(1) and (3) of this section apply.

* * * * *

■ 48. Section 414.1425 is amended by—

■ a. Revising paragraph (c)(5) and (6), (d)(3) and (4); and

■ b. Adding paragraph (d)(5).

The revision and addition reads as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(c) * * *

(5) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(6) Beginning in the 2020 QP Performance Period, an eligible clinician is not a QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities.

* * * * *

(d) * * *

(3) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; or

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.

(4) Beginning in the 2020 QP Performance Period, an eligible clinician is not a Partial QP for a year if:

(i) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities; or

(ii) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM, and the eligible clinician does not individually achieve a Threshold Score that meets or exceeds the Partial QP payment amount threshold or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities.

(5) Beginning in the 2020 QP Performance Period, Partial QP status applies only to the TIN/NPI combination(s) through which Partial QP status is attained.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTING

■ 49. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 50. Section 415.172 is amended by revising the section heading and paragraph (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

* * * * *

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

* * * * *

■ 51. Section 415.174 is amended by—

■ a. Revising paragraph (a)(6); and

■ b. Removing and reserving paragraph (b).

The revision reads as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) * * *

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter to each beneficiary in accordance with the documentation requirements at § 415.172(b).

(b) [Reserved]

PART 416—AMBULATORY SURGICAL CENTERS

■ 52. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 416.42 [Amended]

■ 53. Section 416.42 is amended in paragraph (a)(1), by removing the phrase ''A physician must'' and by adding in its place the phrase ''A physician or an anesthetist as defined at § 410.69(b) of this chapter must''.

PART 418—HOSPICE CARE

■ 54. The authority citation for part 418 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 55. Section 418.106 is amended by revising paragraph (b)(1) to read as follows:

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.

* * * * *

(b) * * *

(1) Drugs may be ordered by any of the following practitioners:

(i) A physician as defined by section 1861(r)(1) of the Act.

(ii) A nurse practitioner in accordance with state scope of practice requirements.

(iii) A physician assistant in accordance with state scope of practice requirements and hospice policy who is:

(A) The patient's attending physician, and

(B) Not an employee of or under arrangement with the hospice.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 56. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 57. Section 424.67 is added to subpart E to read as follows:

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

(a) *General enrollment requirement.* In order for a program or eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) to receive Medicare payment for the provision of opioid use disorder treatment services, the provider must qualify as an OTP (as that term is defined in § 8.2 of this title) and enroll in the Medicare program under the provisions of subpart P of this part and this section.

(b) *Specific requirements and standards for enrollment.* To enroll in the Medicare program, an OTP must meet all of the following requirements and standards:

(1) Fully complete and submit the Form CMS–855B application (or its successor application) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

(i) Maintain and submit to CMS (via the applicable supplement or attachment) a list of all physicians and eligible professionals who are legally authorized to prescribe, order, or dispense controlled substances on behalf of the OTP. The list must include the physician's or eligible professional's:

(A) First and last name and middle initial.

(B) Social Security Number.

(C) National Provider Identifier.

(D) License number (if applicable).

(ii) Certifying via the CMS–855B and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in paragraphs (b) and (d) of this section. application) and any applicable supplement thereto to its applicable Medicare contractor.

(2) Comply with the application fee requirements in § 424.514.

(3) Successfully complete the high categorical risk level screening required under § 424.518(c).

(4)(i) Have a current, valid certification by SAMHSA for an opioid treatment program consistent with the provisions and requirements § 8.11 of this title.

(ii) A provisional certification under § 8.11(e) of this title does not meet the requirements of the paragraph (b)(4)(i) of this section.

(5) Report on the Form CMS–855 and/or any applicable supplement all OTP staff that meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

(i) Medical director (as described in § 8.2 of this title).

(ii) Program sponsor (as described in § 8.2 of this title).

(6)(i)(A) Must not employ or contract with a prescribing or ordering physician or eligible professional or with any individual legally authorized to dispense narcotics who, within the preceding 10 years, has been convicted (as that term is defined in 42 CFR 1001.2) of a federal or state felony that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries based on the same categories of detrimental felonies, as well as case by case detrimental determinations, found at § 424.535(a)(3).

(B) Paragraph (b)(6)(i)(A) of this section applies regardless of whether the individual in question is:

(*1*) Currently dispensing narcotics at or on behalf of the OTP; or

(*2*) A W–2 employee of the OTP.

(ii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who is revoked from Medicare under § 424.535 or any other applicable section in Title 42, or who is on the preclusion list under § 422.222 or § 423.120(c)(6) of this chapter.

(iii) Must not employ or contract with any personnel (regardless of whether the individual is a W–2 employee of the OTP) who has a prior adverse action by a state oversight board, including, but not limited to, a reprimand, fine, or restriction, for a case or situation involving patient harm that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. CMS will consider the factors enumerated at § 424.535(a)(22) in each case of patient harm that potentially applies to this paragraph.

(7)(i) Sign (and adhere to the term of) a provider agreement in accordance with the provisions of 42 CFR part 489.

(ii) An OTP's appeals under 498 of a Medicare revocation (under § 424.535) and a provider agreement termination (under § 489.53(a)(1)) must be filed jointly and, as applicable, considered jointly by CMS under part 498 of this chapter.

(8) Comply with all other applicable requirements for enrollment specified in this section and in subpart P of this part.

(c) *Denial of enrollment.* CMS may deny an OTP's enrollment application on any of the following grounds:

(1) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement in this section.

(2) Any of the denial reasons in § 424.530 applies.

(3) An OTP may appeal the denial of its enrollment application under part 498 of this chapter.

(d) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, an OTP—

(i) Must remain validly certified by SAMHSA as required under § 8.11 of this title.

(ii) Remains subject to, and must remain in full compliance with, the provisions of subpart P of this Part and of this section. This includes, but is not limited to, the provisions of paragraph (b)(6) of this section, the revalidation provisions in § 424.515, and the deactivation and reactivation provisions in § 424.540.

(iii) Upon revalidation, successfully complete the moderate categorical risk level screening required under § 424.518(b).

(2) CMS may revoke an OTP's enrollment on any of the following grounds:

(i) The provider does not have a current, valid certification by SAMSHA as required under paragraph (b)(4)(i) or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraph (b)(6) and (d)(1) of this section.

(ii) Any of the revocation reasons in § 424.535 applies.

(3) An OTP may appeal the revocation of its enrollment under part 498 of this title.

(e) *Claim payment.* For an OTP to receive payment for furnished drugs:

(1) The prescribing or medication ordering physician's or other eligible professional's National Provider Identifier must be listed on Field 17 of the Form CMS–1500; and

(2) All other applicable requirements of this section, this part, and part 8 of this title must be met.

(f) *Relation to part 8 of this title.* Nothing in this section shall be construed as:

(1) Supplanting any of the provisions in part 8 of this title; or

(2) Eliminating an OTP's obligation to maintain compliance with all applicable provisions in part 8 of this title.

■ 58. Section 424.502 is amended by adding the definition of ''State oversight board'' in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

State oversight board means, for purposes of §§ 424.530(a)(15) and 424.535(a)(22) only, any state administrative body or organization, such as (but not limited to) a medical board, licensing agency, or accreditation body, that directly or indirectly oversees or regulates the provision of health care within the State.

* * * * *

■ 59. Section 424.518 is amended by adding paragraphs (b)(1)(xii) and (c)(1)(iv) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(b) * * *

(1) * * *

(xii) Revalidating opioid treatment programs.

* * * * *

(c) * * *

(1) * * *

(iv) Prospective (newly enrolling) opioid treatment programs.

* * * * *

■ 60. Section 424.520 is amended by revising paragraph (d) introductory text to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs.* The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs is the later of—

* * * * *

■ 61. Section 424.521 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, and opioid treatment programs.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, or opioid treatment program has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to —

* * * * *

■ 62. Section 424.530 is amended by reserving paragraphs (a)(12),(13) and (14) and adding paragraph (a)(15) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

* * * * *

(a) * * *

(15) *Patient Harm.* The physician or eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or eligible professional conduct that led to patient harm. In determining whether a denial is appropriate, CMS considers the following factors:

(i) The nature of the patient harm.

(ii) The nature of the physician's or eligible professional's conduct.

(iii) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or eligible professional by the State oversight board, IRO, Federal or State health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(A) License restriction(s) pertaining to certain procedures or practices.

(B) Required compliance appearances before State oversight board members.

(C) Required participation in rehabilitation or mental/behavioral health programs.

(D) Required abstinence from drugs or alcohol and random drug testing.

(E) License restriction(s) regarding the ability to treat certain types of patients (for example, cannot be alone with members of a different gender after a sexual offense charge).

(F) Administrative/monetary penalties.

(G) Formal reprimand(s).

(iv) If applicable, the nature of the IRO determination(s).

(v) The number of patients impacted by the physician's or eligible professional's conduct and the degree of harm thereto or impact upon.

(vi) Any other information that CMS deems relevant to its determination.

* * * * *

■ 63. Section 424.535 is amended by—

■ a. In paragraph (a)(14) introductory text, by removing the phrase ''prescribing Part D drugs'' and adding in its place the phrase ''prescribing Part B or D drugs''; and

■ b. Reserving paragraphs (a)(15) through (21).

■ c. Adding paragraph (a)(22).

The addition reads as follows:

§ 424.535 Revocation of enrollment in the Medicare programs.

(a) * * *

(22) *Patient Harm.* The physician or eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or eligible professional conduct that led to patient harm. In determining whether a revocation is appropriate, CMS considers the following factors:

(i) The nature of the patient harm.

(ii) The nature of the physician's or eligible professional's conduct.

(iii) The number and type(s) of sanctions or disciplinary actions that have been imposed against the physician or eligible professional by the State oversight board, IRO, federal or state health care program, or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care. Such actions include, but are not limited to in scope or degree:

(A) License restriction(s) pertaining to certain procedures or practices.

(B) Required compliance appearances before State medical board members.

(C) Required participation in rehabilitation or mental/behavioral health programs.

(D) Required abstinence from drugs or alcohol and random drug testing.

(E) License restriction(s) regarding the ability to treat certain types of patients

(for example, cannot be alone with members of a different gender after a sexual offense charge).

(F) Administrative or monetary penalties.

(G) Formal reprimand(s).

(iv) If applicable, the nature of the IRO determination(s).

(v) The number of patients impacted by the physician's or eligible professional's conduct and the degree of harm thereto or impact upon.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 64. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

§ 425.612 [Amended]

■ 65. Section 425.612 is amended in paragraph (a)(1)(v)(E) introductory text by removing the phrase ''paragraph (a)(1)(v)(B)'' and adding in its place the phrase ''paragraph (a)(1)(v)(D)''.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 66. The authority citation for part 489 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 67. Section 489.2 is amended by adding paragraphs (b)(10) and (c)(3) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) * * *

(10) Opioid treatment programs (OTPs).

(c) * * *

(3) OTPs may enter into provider agreements only to furnish opioid use disorder treatment services.

■ 68. Section 489.10 is amended by revising paragraph (a) to read as follows:

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter. The OTPs must meet the requirements set forth in this section and elsewhere in this chapter.

* * * * *

■ 69. Section 489.13 is amended by revising paragraph (a)(2)(i) to read as follows:

§ 489.13 Effective date of agreement or approval.

(a) * * *

(2) * * *

(i) For an agreement with a community mental health center (CMHC), opioid treatment program (OTP), or a federally qualified health center (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the CMHC, OTP or FQHC meets all Federal requirements.

* * * * *

■ 70. Section 489.53 is amended by revising paragraph (a)(3) to read as follows:

§ 489.53 Termination by CMS.

(a) * * *

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI, it no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter. In the case of an OTP, it no longer meets the requirements set forth in this section and elsewhere in this chapter.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 71. The authority citation for part 498 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 72. Section 498.2 is amended in the definition of ''Provider'' by revising the introductory text and adding paragraph (3) to read as follows:

§ 498.2 Definitions.

Provider means any of the following:

* * * * *

(3) An entity that has in effect an agreement to participate in Medicare but only to furnish opioid use disorder treatment services.

* * * * *

Dated: June 21, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 18, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

APPENDIX 1: PROPOSED MIPS QUALITY MEASURES

NOTE: Except as otherwise proposed in this proposed rule, previously finalized measures and specialty measure sets will continue to apply for the 2022 MIPS payment year and future years. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF # / eCQM NQF #.

TABLE Group A: New Quality Measures Proposed for Addition for the 2022 MIPS Payment Year and Future Years

A.1 International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
Numerator:	Patients with a documented improvement of at least 3 points in their urinary symptom score during the measurement period.
Denominator:	Equals Initial Population. Initial population is: Male patients with an initial diagnosis of benign prostatic hyperplasia, 6 months prior to, or during the measurement period, and a urinary symptom score assessment within 1 month of initial diagnosis and a follow-up urinary symptom score assessment within 6-12 months, who had a qualifying visit during the measurement period.
Exclusions:	Denominator: Patients with urinary retention that starts within 1 year of initial BPH diagnosis; Patients with an initial BPH diagnosis that starts during, or within 30 days of hospitalization; Patients with a diagnosis of morbid obesity, or with a BMI Exam >40 before the follow up urinary symptom score.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	eCQM Specifications
Rationale:	This measure is being proposed because it represents a patient reported outcome by evaluating the patient's response regarding their symptoms associated with the diagnosis of Benign Prostatic Hyperplasia (BPH). Results can be used by clinicians in evaluating whether the patient's symptoms from BPH have improved during the 6 to 12 months after diagnosis and treatment of this disease. The measure was evaluated by the MAP and it was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. Measure information provided by the measure developer indicates IPSS and AUA-SI are statistically valid and reliable symptom scores. The IPSS was adopted by the World Health Organization in 1993. The AUA-SI was developed and validated by the American Urological Association in 1992. The IPSS uses the same questions as the AUA-SI, but also adds a disease-specific quality of life question (OLeary, 2005). It is a reproducible, validated index designed to determine disease severity and response to therapy (DSilva, 2014). Based on the information provided by the measures steward, we believe the measure is evidence-based and represents an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

A.2. Multimodal Pain Management

Category	Description
NQF #: / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.
Measure Steward:	American Society of Anesthesiologists (ASA)
Numerator:	Patients for whom multimodal pain management is administered in the perioperative period from 6 hours prior to anesthesia start time until discharged from the post-anesthesia care unit.
Denominator:	Patients, aged 18 years and older, who undergo selected surgical procedures
Exclusions:	Emergent Cases
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes (Opioid-related)
Collection Type:	MIPS CQMs Specifications
Rationale:	This measure is being proposed because it encourages clinicians to effectively manage patients' pain using multimodal strategies, which in turn can significantly reduce unnecessary opioid use, excessive post-operative prescriptions, and length of stay. We believe there is an urgent need for measures that address the opioid epidemic affecting the nation. It is imperative to include measures in MIPS that support healthy outcomes for patients using opioids. The clinical action being evaluated within this measure supports the reduction in use of opioids for patients in the perioperative treatment of pain. The measure was updated from what was submitted to the MAP following feedback from stakeholders and NCQA's Technical Expert Panel (TEP). The original measure evaluated by the MAP was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. The measure steward indicated that testing data from 503 clinicians for 24,728 cases met the denominator criteria during testing of the measure. The mean performance rate calculated from this data was 74.24 percent with a standard deviation of +/- 0.1492 with a performance range of 0.00 to 100.00. Reliability was assessed at the clinician level and based on data from a large, academic medical center and a Veterans Health Administration facility. In May 2018, the ASA conducted a systematic assessment of face validity among members of its Committee on Pain Medicine and Committee on Regional Anesthesia and Acute Pain Medicine. The 33 respondents indicated a substantial level of agreement supporting this measure's value and validity. Based on the information provided by the measures steward, we believe the measure is evidence-based and represents an important clinical process. The measure steward revised the measure by adding an age criteria and removing elective cases as an inclusion criteria. Upon stakeholder feedback, the denominator eligible cases were expanded to make the measure more applicable to ambulatory settings. Due to this denominator expansion, an age of 18 years and older was added to the denominator criteria as many of the pediatric cases captured by the expanded codes do not require multimodal pain management. Additionally, pediatric patients have a different range of appropriate multimodal pain management options. As such, the measure steward limited the patient population to the clinically relevant adult patient population. A denominator exclusion was added for emergent cases to replace the previous elective surgery requirement for denominator eligibility. The measure steward also stated, citing user feedback, when emergent cases are an exclusion criterion compared to using elective cases as an inclusion criterion, the measure produced more reliable results. We agree that these changes result in a more clinically relevant, reliable, and meaningful measure by expanding the denominator eligible code set to capture all applicable adult patients in different settings and refining the patient population to be in alignment with these changes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

A.3. Adult Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.
Measure Steward:	National Committee for Quality Assurance
Numerator:	Numerator 1: Members in Denominator 1 (D1) who received an influenza vaccine on or between July 1 of the year prior to the measurement period and June 30 of the measurement period. Numerator 2: Members in D2 who received at least 1 Td vaccine or 1 Tdap vaccine between 9 years prior to the start of the measurement period and the end of the measurement period. Numerator 3: Members in D3 who received at least 1 dose of the herpes zoster live vaccine or 2 doses of the herpes zoster recombinant vaccine anytime on or after the members 50th birthday. Numerator 4: Members in D4 who were administered both the 13-valent pneumococcal conjugate vaccine and the 23-valent pneumococcal polysaccharide vaccine at least 12 months apart, with the first occurrence after the age of 60. Numerator 5: The actual number of required immunizations administered to members in D5.
Denominator:	Denominator 1: Members age 19 and older at the start of the measurement period. Denominator 2: Members age 19 and older at the start of the measurement period. Denominator 3: Members age 50 and older at the start of the measurement period. Denominator 4: Members age 66 and older at the start of the measurement period. Denominator 5: The total number of possible immunizations required for members age 19 and older determined by their age at the start of the measurement period.
Exclusions:	Denominator: Members with any of the following: • Prior anaphylactic reaction to the vaccine or its components any time during or before the measurement period. • History of encephalopathy within seven days after a previous dose of a Td-containing vaccine. • Active chemotherapy during the measurement period. • Bone marrow transplant during the measurement period. • History of immunocompromising conditions, cochlear implants, anatomic or functional asplenia, sickle cell anemia & HB-S disease or cerebrospinal fluid leaks any time during the member's history prior to or during the measurement period. • In hospice or using hospice services during the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(v)of the Act)
High priority measure:	No
Collection Type:	MIPS CQMs Specifications, CMS Web Interface Measure Specifications
Rationale:	We are proposing this preventive immunization measure because it is a comprehensive evaluation for compliance with recommended adult vaccinations and supports the 2019 adult immunization schedule that has been approved by the CDC, which is based on the recommendation from the Advisory Committee on Immunization Practices. NCQA and the HHS National Vaccine Program Office submitted this measure via Call for Measures to be considered for MIPS implementation. This robust composite measure assesses the quality clinical action regarding the administration of the influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines. The immunizations included within this measure will reduce the prevalence of severe diseases that may be associated with hospitalization and decrease overall health care costs. This measure is consistent with Healthy People 2020 goals, developed by the Centers for Disease Control and Prevention, to promote healthy behaviors, for increasing immunization rates. The measure was evaluated by the MAP, but this entity did not support this composite measure since it had not been analytically tested at the clinician level, but clinically it is evidence-based as required by section 1848(q)(2)(D)(v) of the Act. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients who have been administered influenza, Tdap/Td, herpes zoster, and pneumococcal vaccines by MIPS eligible clinicians. Implementing the measure at the clinician level does not change the medical intent or evidence supporting preventive immunizations for patients. Therefore, we believe implementing the measure at the clinician level will be successful. Currently, MIPS includes three of the four composite measure's components as individual measure analytics. Individual measures: Q110: Preventive Care and Screening: Influenza Immunization; and Q111: Pneumococcal Vaccination Status for Older Adults have been implemented in the MIPS and PQRS programs for a combined total of over seven years. Another component of this composite measure, Q474: Zoster (Shingles) Vaccination, was implemented as a new individual measure in 2019 MIPS and was tested at the clinician and group level prior to submission to the Call for Measures. The administration of the vaccination diphtheria toxoids and acellular pertussis (Tdap), contained in Adult Immunization Status, is also present in the MIPS program as a component within measure Q394: Immunizations for Adolescents. We recognize this measure is specified currently for adolescents, but believe the logic this measure represents is adaptable to the adult population. We believe that the individual measures referenced above represent each component of the Adult Immunization Status composite measure. Additionally, measures Q110 and Q111 have been successfully implemented in all MIPS collection types. This accomplishment supports

Category	Description
	the face validity of these measure concepts and demonstrates the ease in which the composite health plan measure can be adapted for MIPS use. As such, we believe the health plan level version of this measure can be adapted accordingly to suit the program requirements of MIPS. Nonetheless, we will continue to work with the measure steward to obtain additional testing results regarding this composite measure's implementation for programs beyond the health plan level. The measure steward provided the following health plan evidence to support the value of proposing this composite measure as a quality measure. The information is based on commercial and Medicaid plan performance rates for members aged 19-64 and Medicare plan rates for members aged 65 and older. Across the plans, performance rates were as follows: influenza (mean=24 percent, min=3 percent, max=73 percent; Td or Tdap (mean=35 percent, min=1 percent, max=94 percent); zoster (mean=28 percent, min=0.1 percent, max=85 percent); pneumococcal (mean=17 percent, min=1 percent, max=62 percent); and composite (mean=28 percent, min=2 percent, max=79 percent). We believe this evidence represents there is a need to improve adult vaccination coverage. Based on the information provided by CDC in conjunction with the ACIP, we believe the measure is clinically evidence-based and represents an important clinical process Therefore, we maintain that this measure provides a comprehensive assessment of quality adult preventive care and would met the meaningful measure initiative. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

A.4. Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Numerator:	The proportion of a provider's (clinic's or clinician's) patient care episodes that met or exceeded the risk-adjusted predicted Residual Change Score. The Residual Change Score is defined as the difference between the Actual and Predicted Change Scores where: 1. The Actual Score is the patient's Functional Status (FS) Score; 2. The Actual Change Score is the change in the patient's FS score from Admission to Discharge; and 3. The Predicted Change Score is the risk-adjusted prediction of FS change. (Please see the Comments section of JIRA submission for details of the Risk-adjustment component.) Calculating the Residual Change Score, Example: • Actual Score at Admission = 45 • Actual Score at Discharge = 60 ○ Actual Change Score (Discharge minus Admission) = +15 ○ Predicted Change Score = +10 • Residual Change Score (Actual Change minus Predicted) = +5 Numerator Options: • Performance Met = The Residual Change Score is equal to or greater than 0 • Performance Not Met = The Residual Change Score is less than 0 Performance may be calculated on 3 levels as follows: 1. Patient Level: For the individual patient episode, the patient's Actual FS scores relative to the risk-adjusted predicted. This level should be used for optimizing care as described below.* 2. Clinician Level: The average of the Residuals for patient care episodes managed by a clinician (individual provider) over a 12 month time period. 3. Clinic Level: The average of the Residuals for patient care episodes managed by a group of clinicians within a clinic over a 12 month time period. * A provider's (clinician's or clinic's) performance must be assessed based on an average all of the provider's patient episodes. On the level of the individual patient, variation is expected. When an individual episode does not result in meeting or exceeding the performance standard, the functional data should be useful to the provider in optimizing the balance of effectiveness/efficiency for that particular care episode. For example, if patient-perceived function is not improving, or has plateaued in progress, that data may be a component of provider-patient communication and care decision-making such as the following examples: 1. Does the provider understand the patient's perception of his/her current level of function? 2. Should the treatment plan be modified? 3. Should the patient be discharged sooner than later? 4. Should the patient be referred to a different care provider?
Denominator:	Patients aged 14+ who initiated rehabilitation therapy, chiropractic, or medical episodes of care for neck impairments including but not limited to cervical (neck) pain, radiculopathy, strain, sprain, stenosis, myelopathy, spondylosis or disc disorders.
Exclusions:	None
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High priority measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications

Category	Description
Rationale:	We are proposing this measure because neck pain is prevalent, impacts functional ability and productivity, and is costly. Measurement results can be used by clinicians in evaluating whether the patient's functional status has improved with initiation of rehabilitation therapy. The measure was evaluated by the MAP conditionally and it was supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required in section 1848(q)(2)(D)(v) of the Act. The measure steward indicated that this measure offers ample room for improvement for performance based on testing data. The results from testing were that for 1378 clinics, 24.24 percent were classified as low performers, 60.01 percent as average, and 15.75 percent as high. The measure steward believed and we agree that having only 15.75 percent classified as high leaves more than adequate room for improvement in eligible clinician performance over time. Based on the information provided by the measures steward, we believe this measure is evidence-based and represents an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=89244.

TABLE Group AA: New Quality Measure Proposed for Addition for the 2023 MIPS Payment Year and Future Years

In addition to the new quality measures proposed for addition in Table Group A, we are proposing to add one administrative claims based quality measure for the 2023 MIPS payment year and future years. Quality measures that are specified through the administrative claims collection type do not require separate data submission to CMS. Administrative claims measures are calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims. We are proposing to add this administrative claims-based measure beginning with the 2023 MIPS payment year to allow for time to further refine the measure analytics prior to implementation within the program.

AA.1. All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions

Category	Description
NQF # / eCQM NQF #:	TBD
Quality #:	TBD
Description:	Risk-adjusted outcome measure that uses the outcome of acute, unplanned admissions (per 100 person-years at risk of admission) to assess care quality. Includes Medicare fee-for-service beneficiaries aged 65 years or older who have two or more of the following nine chronic conditions: (1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack. The measure adjusts for: • Demographic variables, clinical comorbidities, and measures of frailty/disability. • Two social risk factors: (1) The Agency for Healthcare Research and Quality Socioeconomic Status Index (AHRQ SES Index) and (2) density of physician specialists. The AHRQ SES Index is a widely used and validated measure of area deprivation derived from the American Community Survey (ACS) census block group-level data and linked to a patient's ZIP code. It summarizes SES measures of employment, income, education, and housing.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Risk-standardized acute admissions per 100 person-years at risk for admission
Denominator:	Medicare fee-for-service beneficiaries ≥ 65 years of age with ≥ 2 of 9 chronic conditions: (1) Acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia (3) Atrial fibrillation (4) Chronic kidney disease (5) Chronic obstructive pulmonary disease or asthma (6) Depression (7) Diabetes (8) Heart failure (9) Stroke or transient ischemic attack
Exclusions:	Denominator Exclusions: (1) Patients without continuous enrollment in Medicare Part A or Part B during the measurement period. (2) Patient was in hospice at any time during the year prior to the measurement year or at start of the measurement year. (3) Patient had no Evaluation and Management visit to a MIPS eligible clinician. Numerator Exclusions: (1) Planned admissions (2) Other admissions that likely do not reflect the quality of ambulatory chronic disease management and primary care provided by the included eligible clinicians: • Complications of procedures or surgeries • Accidents • Injuries • Admissions directly from a skilled nursing facility or acute rehabilitation facility • Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility • Admissions that occur while patients are enrolled in Medicare's hospice benefit
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Rationale:	We are proposing this risk-adjusted administrative claims measure to assess Medicare aged > 65 patients who have two or more of the following nine chronic conditions: (1) acute myocardial infarction, (2) Alzheimer's disease and related disorders or senile dementia, (3) atrial fibrillation, (4) chronic kidney disease, (5) chronic obstructive pulmonary disease or asthma, (6) depression, (7) diabetes, (8) heart failure, and (9) stroke or transient ischemic attack. More than two-thirds of Medicare beneficiaries have been diagnosed with or treated for two or more chronic conditions. People with multiple chronic conditions (MCCs) are more likely to be admitted to the hospital than those without chronic conditions or with a single chronic condition. Additionally, they are more likely to visit the emergency department, use post-acute care (such as skilled nursing facilities), and require home health assistance based on the CMS Chronic Conditions among Medicare Beneficiaries Chartbook: 2012 Edition (cited in ACO 38 measure information form). This measure promotes improved MCC management and coordinated care by assessing the unplanned hospital admissions for this high-risk population. The measure is specified through the administrative claims collection type that does not require separate data submission to CMS. This administrative claims measure

Category	Description
	is calculated based on data available from MIPS eligible clinicians' billings on Medicare Part B claims as well as hospital inpatient, outpatient, and physician claims for clinical risk adjustment. It uses the outcome of acute, unplanned admissions (per 100 person-years at risk of admission) to assess care quality. This measure would be added for the 2023 MIPS payment year to allow time to work through operational factors of implementing the measures. This measure is included in the CY 2020 PFS proposed rule for stakeholder comment.

TABLE Group B: New Specialty Measures Sets Proposed for Addition and Previously Finalized Specialty Measure Sets Proposed for Modification for the 2022 MIPS Payment Year and Future Years

We are proposing to add seven new specialty measures sets: Endocrinology, Nutrition/Dietician, Pulmonology, Chiropractic Medicine, Clinical Social Work, Audiology, and Speech Language Pathology. These sets are proposed to be added based in part on the expanded definition of the MIPS eligible clinician for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. In addition, we have received stakeholder feedback requesting additional specialty sets for clinician types whom did not have an existing specialty measures set. We are soliciting comment on applicable measures for a Clinical Social Work specialty set in the event clinical social workers are proposed for inclusion in the definition of a MIPS eligible clinician in future rulemaking. We are also proposing to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), existing measures with substantive changes for the 2019 MIPS performance period described in Table Group DD are noted with a double asterisk (**), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to fully represent the regulatory definition of high priority measures. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table B as follows: NQF # / eCQM NQF #.

The definition of high priority at § 414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

The following specialty measure set has been excluded from this group because we are not proposing any changes to this specialty measure set: Interventional Radiology. Therefore, we refer readers to the CY 2018 Quality Payment Program final rule for the previously finalized Interventional Radiology specialty measure set (82 FR 54098 through 54099).

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication (2) Percentage of patients who were ordered at least two of the same high-risk medication.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES PROPOSED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Allergy/Immunology specialty set as it is clinically relevant to this clinician type.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ALLERGY/IMMUNOLOGY SET Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis	Health Resources and Services Administration	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale. In addition, we propose to remove this measure from the specialty set because it is not applicable to this specialty as Allergy/Immunology specialists do not diagnose, treat or manage HIV/AIDS patients.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Anesthesiology specialty set.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0236	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	2726	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	2681	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Patient Safety)	N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists

B.2. Anesthesiology

MEASURES PROPOSED FOR **ADDITION** TO THE ANESTHESIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS cCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Opioid)	N/A	TBD	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management**: Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Anesthesiology specialty set as it is clinically relevant to this clinician type.

B.3a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable.

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
! (Efficiency)	N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period	American College of Cardiology
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.3b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Electrophysiology Cardiac Specialist measure set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Electrophysiology Cardiac Specialist measure set.

B.3b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* !	N/A	348	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	American College of Cardiology Foundation
* !	2474	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
* !	N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.4. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroenterological Association
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month submission period.	American Gastroenterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Efficiency)	N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Effective Clinical Care	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association

B.4. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GASTROENTEROLOGY SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0659	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy	American Gastroenterological Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened to prevent overuse of X-ray assessment	American Gastroenterological Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate**: The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy	American Society for Gastrointestinal Endoscopy	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.5. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.5. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Foundation (PCPI®)

B.5. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment	American Academy of Dermatology
* ! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.6. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS128 v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	/Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
§ * ! (Appropriate Use)	N/A	066	CMS146v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0104e	107	CMS161v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	2372 / N/A	112	CMS125v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling Hlgh Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
* ! (Opioid)	N/A	305	CMS137 v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	N/A	309	CMS124 v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last IIIV viral load test during the measurement year.	Health Resources and Services Administration
* ! (Outcome)	0209	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710 / 0710e	370	CMS159 v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communica tion and Care Coordinatio n	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A	377	CMS90v 9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermedi ate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	1407	394	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month submission period.	American Gastroenterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347 v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16 20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Appropriate Use)	N/A	472	CMS249 v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.6. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Family Medicine specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	Centers for Disease Control and Prevention	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v 8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.6. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.7. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS12 8v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS13 1v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS13 4v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American College of Cardiology Foundation
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A	305	CMS137v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	N/A	309	CMS124v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) •• Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* ! (Outcome)	0209	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710 / 0710e	370	CMS15 9v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A	377	CMS90 v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month submission period.	American Gastro-enterological Association
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* ! (Appropriate Use)	N/A	472	CMS249v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.7. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	Centers for Disease Control and Prevention	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type.

B7. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults**: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination**: The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.8. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A	066	CMS146 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis**: Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0104e	107	CMS161 v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
	N/A	254	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery
* ! (Efficiency)	N/A	415	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.8. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE EMERGENCY MEDICINE SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	255	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.9. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
§	N/A	309	CMS124v8	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A	310	CMS153 v8	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordinatio n)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communicat ion and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture	National Committee for Quality Assurance
! (Patient Safety)	2063	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecolog ic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining A Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16 20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A	472	CMS249 v2	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349 v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.9. Obstetrics/Gynecology

PROPOSED FOR **ADDITION** TO THE OBSTETRICS/GYNECOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type and drives quality of care by assessing the rate of elective deliveries before 39 weeks gestation in the absence of medical indication, following The American College of Obstetrics and Gynecology clinical guidance.
* ! (Care Coordination)	N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, and family and contraceptive planning.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	Centers for Disease Control and Prevention	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Obstetrics/Gynecology specialty set as it is clinically relevant to this clinician type.

B.9. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines.	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.10. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology specialty set.

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0086 / 0086e	012	CMS143v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0087	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	0089 / 0089e	019	CMS142v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF #/ eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0563	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12 month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.10. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	1536	303	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome) *	N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.10. Ophthalmology

MEASURES PROPOSED FOR **ADDITION** TO THE OPHTHALMOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS cCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology	We propose to include this measure in the Ophthalmology specialty set as it is applicable to this clinician type and drives quality of care by assessing patient satisfaction following cataract surgery.

B.10. Ophthalmology

PREVIOSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OPHTHALMOLOGY SET Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0564 / 0564e	192	CMS132 v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures**: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy):** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.11. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69 v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v 9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone $\geq$ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period	National Committee for Quality Assurance
! (Care Coordination)	N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	375	CMS66 v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	376	CMS56 v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
*	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy/Laminotomy:** The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure	Minnesota Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Fusion Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of age and older who had a lumbar fusion procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	470	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Total Knee Replacement Surgery:** The average change (preoperative to postoperative) in functional status using the Oxford Knee Score (OKS) for patients age 18 and older who had a primary total knee replacement.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Fusion Surgery:** The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure	Minnesota Community Measurement

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Orthopedic Surgery specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years + with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure)	Focus on Therapeutic Outcomes, Inc.	This measure is proposed for inclusion into the Orthopedic Surgery specialty set as it is clinically relevant and the denominator was expanded to allow for this clinician type.

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MEASURES PROPOSED FOR **ADDITION** TO THE ORTHOPEDIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Orthopedic Surgery specialty set as it is clinically relevant to this clinician type.

B.11. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ORTHOPEDIC SURGERY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claim Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ORTHOPEDIC SURGERY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet**: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	American Association of Hip and Knee Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.12. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Nec Surgery
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ** §	0028 / 0028e	226	CMS13 8v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS13 9v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Nec Surgery
* ! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Nec Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Nec Surgery
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.12. Otolaryngology

PROPOSED FOR **ADDITION** TO THE OTOLARYNGOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Otolaryngology specialty set as it is clinically relevant to this clinician type.

B.12. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OTOLARYNGOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.13. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pathology specialty set.

B.13. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.	College of American Pathologists

B.13. Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology	This measure is proposed for inclusion into the Pathology specialty set as it is applicable to a subset of pathologists and drives care coordination and communication.

B.13. Pathology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PATHOLOGY SET Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
1854	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.14. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set.

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A	066	CMS146v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A	239	CMS155v8	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A	240	CMS117v8	eCQM Specifications	Process	Community / Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A	305	CMS137v8	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	N/A	310	CMS153v8	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	366	CMS136v9	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
*	N/A	379	CMS74v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	1407	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.14. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	NA	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.14. Pediatrics

MEASURES PROPOSED FOR **ADDITION** TO THE PEDIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0710 / 0710e	370	CMS159 v8	eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (−/- 60 days) after an index event date.	Minnesota Community Measurement	We propose to include this measure in the Pediatrics specialty set as the denominator was expanded to include pediatric patients and it drives quality by measuring depression remission.

B.14. Pediatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PEDIATRICS SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	Health Resources and Services Administration	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	467	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the 12 months preceding or on their first, second, or third birthday. This is a composite measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened in the 12 months preceding or on their first, second or third birthday.	Oregon Health & Science University	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.15. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set.

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421 e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419 e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028 e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.15. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL MEDICINE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Ostcoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.16. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set.

B.16. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.16. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.17. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	438	CMS347v3	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.17. Preventive Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE PREVENTIVE MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Preventive Medicine specialty set as a replacement for measure Q109: Osteoarthritis (OA): Function and Pain Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q109, but is more robust in that it requires more frequent assessment and a plan of care.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Preventive Medicine specialty set as it is clinically relevant to this clinician type.

B.17. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127v8	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.18. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set.

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	268	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.	American Academy of Neurology
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.	American Academy of Neurology
	N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.	American Academy of Neurology
! (Care Coordination)	N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months	American Academy of Neurology
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, (Screener and Opioid Assessment for Patients with Pain, revised) SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
! (Efficiency)	N/A	419	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12 month measurement period AND whose health related quality of life score stayed the same or improved.	American Academy of Neurology

B.18. Neurology

MEASURES PROPOSED FOR **ADDITION** TO THE NEUROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Neurology specialty set as a replacement for measure Q282: Dementia: Functional Status Assessment, which is being proposed for removal. Measure Q182 includes the patient population in measure Q282, but is more robust in that it requires more frequent assessment and a plan of care.

B.18. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.19. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Mental/Behavioral Health specialty set.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	009	CMS128 v8	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	0104e	107	CMS161 v8	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/P opulation Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	366	CMS136v9	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days after discharge. ● The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	2803	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.19. Mental/Behavioral Health

MEASURES PROPOSED FOR **ADDITION** TO THE MENTAL/BEHAVIORAL HEALTH SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Mental/Behavioral Health specialty set as a replacement for measure Q282: Dementia: Functional Status Assessment, which is being proposed for removal. Proposed changes to the measure requested by the measure steward include adding this clinician type to the measure so that measure Q182 will include the patient population in measure Q282. Measure Q182 is more robust in that it requires more frequent assessment and a plan of care.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE MENTAL/BEHAVIORAL HEALTH SET

Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	325	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0712e	371	CMS160v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table for rationale.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE MENTAL/BEHAVIORAL HEALTH SET Note: In this proposed rule, CMS proposes removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	Minnesota Community Measurement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.20. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Diagnostic Radiology specialty set.

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Care Coordination)	N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
! (Appropriate Use)	N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology
* ! (Appropriate Use)	N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion < 1.0 cm.	American College of Radiology
! (Appropriate Use)	N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.20. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DIAGNOSTIC RADIOLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign."	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are submitted to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12 month period after the study.	American College of Radiology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.21. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.21. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEPHROLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale
N/A	111	CMS127v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.21. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEPHROLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end -stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.22. General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set.

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421 e	128	CMS69 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419 e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.22. General Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE GENERAL SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons	We propose to include this measure in the General Surgery specialty set as it is clinically relevant to this clinician type.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the General Surgery specialty set as it is clinically relevant to this clinician type.

B.22. General Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GENERAL SURGERY SET Note: In this proposed rule, CMS proposes the removal the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table for rationale.

B.23. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
* ! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.23. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE VASCULAR SURGERY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive**: Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive**: Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale
1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive**: Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.24. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set.

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0129	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0114	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* ** §	0028 / 0028 c	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	0119	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.24. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE THORACIC SURGERY SET

Note: In this proposed rule, CMS proposes the removal the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.25. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0390	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research
* §	0062 / N/A	119	CMS134 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society

B.25. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
*	N/A	462	CMS645 v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.25. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	TBD	CMS771 v1	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-centered Experience and Outcomes	**International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type.

B.25. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SET Note: In this proposed rule, CMS proposes the removal the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence**: Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per American College of Obstetrics and Gynecology (ACOG), American Urogynecologic Society, and American Urological Association guidelines	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.26a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The Oncology specialty set has been updated to include Hematology and has been renamed as Oncology/Hematology. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology specialty set.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157v8	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	1858	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy:** Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.	American Society of Clinical Oncology
§	1859	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	462	CMS645v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.26a. Oncology/Hematology

MEASURES PROPOSED FOR ADDITION TO THE ONCOLOGY/HEMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology	We propose to include this measure in the Oncology/Hematology specialty set as this set was updated to include IIematology for the 2020 performance period and this measure is clinically relevant.
	N/A	069	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.	American Society of Hematology	We propose to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.
	N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Oncology/Hematology specialty set as this set was updated to include Hematology for the 2020 performance period and this measure is clinically relevant.
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Oncology/Hematology specialty set as it is clinically relevant to this clinician type.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ONCOLOLGY/HEMATOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Not Admitted to Hospice (lower score – better):** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.26a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ONCOLOLGY/HEMATOLOGY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.26b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.26b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

B.27. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
*	N/A	475	CMS349v2	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have been tested for HIV within that age range.	Centers for Disease Control and Prevention

B.27. Infectious Disease

MEASURES PROPOSED FOR **ADDITION** TO THE INFECTIOUS DISEASE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Infectious Disease specialty set as it is clinically relevant to this clinician type.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE INFECTIOUS DISEASE SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use**: Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)	We agree with specialty society feedback to remove this measure from this specialty set. Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate testing for children with otitis media with effusion, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.

B.27. Infectious Disease

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INFECTIOUS DISEASE SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	474	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Zoster (Shingles) Vaccination**: The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.28. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests t documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy/Laminotomy:** The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Fusion Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of ag and older who had a lumbar fusion procedure.	Minnesota Community Measurement

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery:** The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure.	Minnesota Community Measurement
* ! (Outcome)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Fusion Surgery:** The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure	Minnesota Community Measurement

B.28. Neurosurgical

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROSURGICAL SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.29. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set.

B.29. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421 / 0421e	128	CMS69v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.29. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.30. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Hospitalists specialty set.

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	2726	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.30. Hospitalists

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE HOSPITALISTS SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	407	N/A	Medicare Part B Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.31. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.31. Rheumatology

PREVIOUSLY FINALISED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A	024	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.31. Rheumatology

PREVIOUSLY FINALISED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
*	N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* ** §	0028 / 0028e	226	CMS138 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* § ! (Outcome)	0018 / N/A	236	CMS165 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance

B.31. Rheumatology

PREVIOUSLY FINALISED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / cCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.31. Rheumatology

MEASURES PROPOSED FOR **ADDITION** TO THE RHEUMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS cCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Rheumatology specialty set as it is clinically relevant to this clinician type.

B.31. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE RHEUMATOLOGY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.32. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dentistry specialty set.

B.32. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A	378	CMS75v8	eCQM Specifications	Outcome	Community/ Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A	379	CMS74v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.33. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure**	**Indicator**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.33. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.33. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	2872e	281	CMS149 v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
! (Patient Safety)	0101 / N/A	318	CMS139 v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We propose to include this measure into the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

B.33. Physical Therapy/Occupational Therapy

MEASURES PROPOSED FOR **ADDITION** TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

B.33. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.34. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2872e	281	CMS149v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF #/ eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology

B. 34. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older**: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose to include this measure into the Geriatrics specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B. 34. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	This measure is being proposed for inclusion into the Geriatrics specialty set as a replacement for measure Q282: Dementia: Functional Status Assessment, which is being proposed for removal. Measure Q182 will include the patient population in measure Q282. Measure Q182 is more robust in that it requires more frequent assessment and a plan of care.
! (Outcome)	N/A	TBD	CMS771v1	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-centered Experience and Outcomes	**International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) change 6-12 months after diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type.

B. 34. Geriatrics

MEASURES PROPOSED FOR **ADDITION** TO THE GERIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status:** Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Geriatrics specialty set as it is clinically relevant to this clinician type.

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GERIATRICS SET

Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization**: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.34. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE GERIATRICS SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.35. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0069 / N/A	065	CMS154 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode.	National Committee for Quality Assurance
§ * ! (Appropriate Use)	N/A	066	CMS146 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
! (Patient Safety)	0419 / 0419e	130	CMS68v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population IIealth	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	317	CMS22v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropri ate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Appropri ate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropri ate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2803	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Appropriate Use)	0657	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.35. Urgent Care

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE URGENT CARE SET Note: In this this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
0420	131	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.36. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0083 / 0083e	008	CMS144 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
*	N/A	317	CMS22v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
* §	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American College of Cardiology

B. 36. Skilled Nursing Facility

MEASURES PROPOSED FOR **ADDITION** TO THE SKILLED NURSING FACILITY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD	N/A	CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type.

B.36. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE SKILLED NURSING FACILITY SET Note: In this proposed rule, CMS proposes the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2022 MIPS Payment Year. See Table C for rationale.

B.37. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Endocrinology specialty set.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* §	0055 / N/A	117	CMS131v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0062 / N/A	119	CMS134v8	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053	418	N/A	Medicare Part B Claims Measure Specifications , MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	N/A	438	CMS347v3	eCQM Specifications , CMS Web Interface Measure Specifications , MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	N/A	462	CMS645v3	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute	We propose to include this measure in the Endocrinology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.37. Endocrinology

MEASURES PROPOSED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A	TBD		CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Adult Immunization Status**: Percentage of members 19 years of age and older who are up-to-date on recommended routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal.	National Committee for Quality Assurance	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.

B.38. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Nutrition/Dietician specialty set.

B.38. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Outcome)	0059 / N/A	001	CMS122 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (IIbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
* §	0421 / 0421c	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
! (Patient Safety)	0419 / 0419c	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.

B.38. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
§	N/A	239	CMS155 v8	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Nutrition/Dietician specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Pulmonology specialty set.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	0102	052	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* §	0421 / 0421e	128	CMS69v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and < 25 kg/m^2.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
* § ! (Outcome)	0018 / N/A	236	CMS165v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
! (Care Coordination)	N/A	374	CMS50v8	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.39. Pulmonology

MEASURES PROPOSED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	We propose to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Chiropractic Medicine specialty set.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR ADDITION TO THE CHIROPRACTIC MEDICINE SET									
Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Inclusion
* ! (Outcome)	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.40. Chiropractic Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE CHIROPRACTIC MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Outcome)	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.	We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.
! (Outcome)	N/A	TBD	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.	This measure is being proposed as a new measure for the 2020 performance period. We propose to include this measure in the Chiropractic Medicine specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, we are soliciting comment on applicable measures for a Clinical Social Work specialty set, which takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that may be proposed for this new measure set in the event clinical social workers are proposed for inclusion in the definition of a MIPS eligible clinician in future rulemaking. We request comment on the measures available in the Clinical Social Work specialty set.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
	2872e	281	CMS149v8	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
*	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* § ! (Outcome)	0710 / 0710e	370	CMS159v8	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	1365e	382	CMS177v8	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Centers for Medicare & Medicaid Services	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.
	2803	402	NA	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.41. Clinical Social Work

MEASURES PROPOSED FOR **ADDITION** TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Clinical Social Work specialty set as it is clinically relevant to this clinician type.

B.42. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Audiology specialty set.

B.42. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
*	0418 / 0418e	134	CMS2v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.42. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set as it is clinically relevant.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Audiology specialty set as it is clinically relevant and the measure owner is proposing to expand the denominator to include this clinician type.
* ** §	0028 / 0028e	226	CMS138v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

B.42. Audiology

MEASURES PROPOSED FOR **ADDITION** TO THE AUDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness	Audiology Quality Consortium	We propose to include this measure in the Audiology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
! (Patient Safety)	0101 / N/A	318	CMS139v8	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance	We propose to include this measure in the Audiology specialty set as it is clinically relevant.

B.43. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that are proposed for this new measure set. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.43. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Patient Safety)	0419 / 0419e	130	CMS68v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.
* ! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type. The measure owner is also proposing to add coding for this clinician type for the 2020 performance period.
* ! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Speech Language Pathology specialty set based upon stakeholder feedback requesting inclusion in a specialty set for this clinician type. The measure owner is also proposing to add coding for this clinician type for the 2020 performance period.

B.43. Speech Language Pathology

MEASURES PROPOSED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* ** §	0028 / 0028e	226	CMS138 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose to include this measure in the Speech Language Pathology specialty set based upon past stakeholder feedback requesting inclusion in a specialty set for this clinician type.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 55 previously finalized quality measures from the MIPS Program for the 2022 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), additional criteria that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100 percent.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0097	046	N/A	Medicare Part B Claim Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative of previously finalized measure Q130: Documentation of Current Medications in the Medical Record that also addresses assessment of current medications at the time of a patient and eligible clinician encounter. This measure is not only duplicative but includes measure logic that has demonstrated to be historically challenging for implementation by eligible clinicians. This measure is a legacy measure from the Physician Quality Reporting Initiative that was implemented initially as a Medicare Part B claims only measure. With the expansion of collection methods being used in the program, unforeseen implementation challenges have arisen. We believe measure Q130 is the best measure to support the quality outcome of current medications being documented in the medical record. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty sets as it is clinically relevant to these clinician types: Pulmonology and Clinical Social Work.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0091	051	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented.	American Thoracic Society	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program to ensure measures are not duplicative and present an opportunity to provide a meaningful impact to quality. We prefer the more robust, previously finalized measure Q52: Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy that assesses appropriate management of COPD by prescribing a long-acting inhaled bronchodilator for symptomatic patients based on spirometry test results that demonstrate FEV1/FVC < 70 percent, FEV1 < 60 percent, and patient's assessed COPD symptoms. Measure Q51 represents the process having the spirometry results reviewed and documented which is essentially a component of measure Q52. Therefore, we prefer to have eligible clinicians report the more robust measure Q52 which address spirometry results to provide the best option in pharmacological treatment. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Pulmonology.
N/A	068	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy.	American Society of Hematology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because we believe that documentation of iron stores would be considered a standard of care during administration of erythropoietin therapy. We believe this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Oncology/ Hematology.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology-Head and Neck Surgery	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it represents the clinical equivalency of previously finalized measure Q93: Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use. In the circumstance an eligible clinician does not prescribe an antibiotic, most likely a topical therapy would be prescribed. However, the eligible clinician is able to prescribe both an antibiotic and topical and remain numerator compliant for this measure which does not address the overuse of systemic antimicrobial use. Therefore, we believe this measure is not providing a meaningful impact to quality improvement.
N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative of previously finalized measure Q182: Functional Outcome Assessment that also addresses functional assessment and possibly pain depending on which standardized tool utilized. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: add coding for physical therapists and occupational therapists to the list of denominator eligible encounters as well as add this measure to the Physical Therapy/ Occupational Therapy specialty set. The measure steward states and we agree that for individuals with osteoarthritis (OA), physical therapists and occupational therapists provide various interventions with the goals of improving muscle performance, activity and participation, and promoting physical activity. Despite these revisions offered by the measure steward, we believe that it is important to reduce duplicity within the program and prefer the more robust measure Q182 which also supports physical and occupation therapist, more frequent functional assessment, and care plan for identified functional deficiencies.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0041 / 0041e	110	CMS147 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age-appropriate preventive immunizations. We are proposing to remove this measure to be consistent with ensuring measures are not duplicative and present an opportunity to provide a meaningful impact to quality. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: the numerator instructions would be revised to read: "Due to the changing nature of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. If the LAIV is recommended for administration for a particular flu season, an eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting previous receipt, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV)." This would allow clinical discretion and alignment with current performance period's CDC/ACIP guidelines without negatively affecting clinicians providing LAIV.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	111	CMS127 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age-appropriate preventive immunizations. In addition, measure Q111 does not align with the current ACIP guidelines, but was retained for certain collection types to provide a measure selection option that addresses an important population health matter. The proposed measure requires patients to receive both the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) at least 12 months apart, with the first occurrence after the age of 60, whereas measure Q111 only requires the patient to receive either PCV13 or PPSV23 vaccine. In the event, we do not finalize the proposal to remove the measure, we would expand the denominator to include nursing home and domiciliary settings as this would be an applicable patient population.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program due to the controversy surrounding the potential correlation between assessment of pain and increase in prescriptions for opioid medications. After consideration of previous stakeholder feedback, we believe this measure may have the unintended consequence of encouraging excessive prescribing of pharmacologic therapies to assist with pain management. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: expand the denominator to include coding for audiology and speech language pathology MIPS eligible clinicians and remove the denominator exception allowing for patients with severe mental and/or physical incapacities to be excluded from the numerator. The measure steward submitted this substantive change based on a literature search the supports the need for improved pain assessment and follow up in patients with dementia. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments as it is clinically relevant to these clinician types: Chiropractic Medicine, Clinical Social Work, Audiology and Speech Language Pathology. Despite these revisions offered by the measure steward, we believe that it is important to ensure that the MIPS quality measures support the safety of patients and have a meaningful impact on quality management of pain by all eligible clinicians.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign".	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.3 percent for the Medicare Part B Claims specifications collection type and 0.5 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. Average performance rates are based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	160	CMS52v8	eCQM Specifications	Process	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis jiroveci pneumonia (PCP) prophylaxis.	Health Resources and Services Administration	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the numerator with addition of Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis and parenteral pentamidine and oral clindamycin with primaquine to Population one. For Population two and three, we would add intravenous pentamidine to the "Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis" value set. In alignment with these updates, the measure steward has proposed to update and create definitions related to CD4 Count Tests to include oral clindamycin and primaquine for population 1 and update logic in all three numerators to allow for 'Medication Active' documentation in addition to 'Medication, Order' documentation for appropriate capture of either an active or ordered medication. Additionally, we would adopt the measure steward's substantive change to remove Leucovoin as a medication option and add oral Clindamycin to align with guideline updates. Additionally, we would update logic for denominator exceptions in population 1 to reflect "3 months or less after". Additionally, if the measure is not finalized for removal from the MIPS program, we propose to remove the measure from the Allergy/ Immunology specialty set since this measure is not applicable to this specialty as Allergy/Immunology specialists do not diagnose, treat or manage HIV/AIDS patients. In addition, if the measure is retained in the MIPS program based on stakeholder comments we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Pulmonology. Despite these revisions, we believe this measure is not providing a meaningful impact to quality improvement due to lack of adoption by eligible clinicians.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.5 percent for the MIPS CQMs specifications collection type For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in (83 FR 59761 through 59763). The average performance for this inverse measure is 1.3 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is duplicative of previously finalized measure Q182: Functional Outcome Assessment. Measure Q182 does not limit the functional tools utilized for functional assessment, therefore ensuring rheumatologists are able to submit this measure. Additionally, measure Q182 is more robust in quality with inclusion of a follow up plan for identified functional outcome deficiencies. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: revise the numerator statement to: Patients for whom a standardized functional status assessment using an ACR-preferred, patient-reported functional status assessment tool was performed at least once within 12 months. Additionally, we would update the Functional Status Assessment definition to the following: This measure assesses if physicians are using a standardized descriptive or numeric scale, standardized questionnaire, or notation of tool to assessment of the impact of RA on patient activities of daily living. Examples of tools used to assess functional status include but are not limited to: Health Assessment Questionnaire (HAQ), Modified HAQ, HAQ-2, and American College of Rheumatology's Classification of Functional Status in Rheumatoid Arthritis. Functional status should be assessed using a measurement tool assigned preferred status by the ACR. The instruments listed are the ACR-preferred tools that fulfill the measure requirements: PROMIS Physical Function 10-item (PROMIS PF10a), Health Assessment Questionnaire-II (HAQ-II), and Multi-Dimensional Health Assessment Questionnaire (MD-HAQ). Despite these revisions offered by the measure steward, we believe that it is important to reduce duplicity within the program and prefer the more robust measure Q182 which supports more frequent functional assessment and follow up plan for identified functional deficiencies.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because previously finalized measure Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity assesses the same patient population, but requires more frequent assessment in order to be numerator compliant making it a more robust measure.
0659	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association	We propose removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as it is not consistent with current guidelines. It was previously proposed for removal, but was retained to allow for the measure to be updated to align with newly released guidelines. This measure was not updated to align with new guidelines. The measure steward and a co-owner of this measure, AGA, consulted with other co-owners, the American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE), and all agree that measure Q185 should be removed.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0564 / 0564e	192	CMS132 v8	eCQM Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The measure steward did propose to update the language to better clarify how the measure is currently implemented. They also requested to update the denominator exclusion data elements/value sets; removing 'Aphakia and Other Disorders of Lens,' 'Cysts of Iris, Ciliary Body and Anterior Chamber,' 'Enophthalmos,' and 'Prior Pars Plana Vitrectomy' and adding 'Glaucoma Associated with Congenital Anomalies, Dystrophies and Systemic Syndromes,' 'Other Endophthalmitis,' and 'Purulent Endophthalmitis'. We do not believe these changes will have an impact on performance rates and will continue to propose its removal due to being extremely topped out. In addition, the measure steward proposed to update the measure to specify the complication should be assessed of the operative eye. This is an inverse measure with extremely high performance rate of 0.9 percent for eCQM specifications collection type and 0.2 percent for MIPS CQMs collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the eCQM and MIPS CQMs specifications collection types are considered extremely topped out. Average performance rates are based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.	We propose removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as the measure steward, Focus on Therapeutic Outcomes, Inc. (FOTO) no longer supports the inclusion of the measure. The patient population within this measure is captured in the proposed FOTO measure A.4: Functional Status Change for Patients with Neck Impairments. In the event we do not finalize A.4: Functional Status Change for Patients with Neck Impairments, we would maintain this measure with the following substantive changes: update the numerator to require meeting or exceeding the risk adjusted prediction of the functional status change to be a Performance Met, move the current denominator exclusions to denominator exceptions, add denominator exclusion for patients with diagnosis of a degenerative neurological condition at any time before or during the episode of care, and add denominator exceptions for ongoing care not indicated: patient self-discharged early, patient discharged after only 1-2 visits due medical events, patient seen only 1-2 visits. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it represents a structure measure rather than a measure that supports direct patient care. We believe that it is important for eligible clinicians to encourage the development of such systems to track mammography to support patient compliance for adherence of clinical guidelines but systems would likely be implemented by support staff and management. We are striving for more outcome based measures.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1854	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 100 percent for the Medicare Part B Claims specifications collection type and 99.5 percent for the MIPS CQMs specifications collection type. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 99.9 percent for the Medicare Part B Claims specifications collection type and 99.7 percent for the MIPS CQMs specifications collection type. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	255	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED).	American College of Emergency Physicians	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure narrows the eligible patient population to the Rh-Negative pregnant women which has not been able to create a benchmark. This is a result of the limited patient population and measure adoption which does not provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. This does not align with the meaningful measure initiative. We encourage measure stewards to develop a measure that expands the patient population to those that had their Rh Status evaluated in the Emergency Department (ED) and received Rh-immunoglobulin (Rhogam) if Rh-negative.
N/A	262	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Image Confirmation of Successful Excision of Image-Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy.	American Society of Breast Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 100 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.0 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients regardless of age with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened to prevent overuse of X-ray assessment.	American Gastro-enterological Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the substantive changes submitted by the measure steward would require a less meaningful quality action and extend the prednisone usage from 60 to 90 or greater consecutive days. The revised measure's quality action would be simplified to prescribing supplements such as calcium and/or vitamin D optimization. Additionally, the measure steward proposes to replace the term "Loss Assessment" with "Health Optimization" throughout the measure, define the patient population as 18 and over, as well as updating the numerator definition to "Documentation that calcium and/or Vitamin D optimization has been ordered or performed. This includes, but is not limited to, checking serum levels, documenting use of supplements or prescribing supplements" to better align with the measure's intent. The current measure requires a Central Dual-energy X-Ray Absorptiometry (DXA) and documented review of systems and medication history or pharmacologic therapy (other than minerals/vitamins) for osteoporosis prescribed within the past two years. We agree that patients without risk factors would not be appropriate for frequent DXA scans as the current quality measure requires. The measure steward's substantive changes for the measure do not account for patients with high risk factors, which may warrant additional screening and pharmacologic treatment. The measure would be more robust if it was revised to assess based on multiple clinical criteria such as age, risk factors, etc. We encourage the measure steward to submit a new measure that takes into account risk factors and require the appropriate clinical action.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program. Based on input from the measure steward, we propose the substantive change of expanding the denominator to physical therapy in the circumstance that this measure is not finalized for removal. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is maintained within the program: Physical Therapy/ Occupational Therapy and Clinical Social Work. Although, with the denominator expansion of measure Q282 to physical therapy and the proposed inclusion of behavioral health eligible clinicians to the denominator of measure Q182: Functional Outcome Assessment, this measure would be duplicative to broadly applicable and previously finalized measure Q182. Therefore, we support the removal of measure Q282 due to duplicity. We believe that it is important to reduce duplicative measures within the program and prefer the more robust measure Q182 which supports more frequent functional assessment and care plan for identified functional deficiencies.
N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative and shares a denominator with previously finalized measure Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia which requires screening and provision of mitigation recommendations and referral to resources for patients diagnosed with dementia or their caregivers. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: include physical therapy in the denominator of the measure. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments: Physical Therapy/Occupational Therapy and Clinical Social Work. We believe that it is important to reduce duplicity within the MIPS quality measures and support the removal of measure Q288.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	325	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program as we have reexamined public comments received during last year's rulemaking cycle. Stakeholders commented that it is burdensome for clinicians to retrieve specialists' reports for all patient visits. This insinuates the communication may be happening, but the co-morbid treating physician is not looking for and/or considering the MDD status. Additionally, this measure is duplicative to previously finalized measure Q374: Closing the Referral Loop: Receipt of Specialist Report which specifies numerator compliance as receipt of report from the referring eligible clinician. In the event that the measure is maintained, we propose to add this measure to the following specialty sets: Clinical Social Work.
1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited patient population and adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. There were zero submissions for the 2017 performance period.
N/A	329	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set based on stakeholder feedback: Nephrology.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians.
N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate:** The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	American Society for Gastrointestinal Endoscopy	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program after review of previous stakeholder feedback, scoring implications, and attribution to the MIPS eligible clinician. The measure does not account for variables which may influence the adenoma detection rate such as geographic location, socioeconomic status of patient population, community compliance of screening, etc. Due to the measure construct, benchmarks calculated from this measure are misrepresented and do not align with the MIPS scoring methodology where 100 percent indicates better clinical care or control. Guidelines and supplemental literature support a performance target for adenoma detection rate of 25 percent for a mixed gender population (20 percent in women and 30 percent in men). In addition, the measure does not account for MIPS eligible clinicians that fail to detect adenomas, but may score higher based on the patient population.
1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in (81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q344 is a more comprehensive measure accounting for the patient population found within measure Q345 as well as assessing for complications and appropriate length of stay. Based on input from the measure steward, we propose the substantive change of replacing the "or" with "and" in the title and the numerator statement in the circumstance that this measure is not finalized for removal. Despite these revisions, this measure is still duplicative in nature and less comprehensive as compared to measure Q344.

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NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q260: Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2). Measure Q260 is a more comprehensive measure accounting for the patient population found within measure Q346 as well as assessing for complications and appropriate length of stay. Based on input from the measure steward, we propose the substantive change of replacing the "or" with "and" in the title and the numerator statement in the circumstance that this measure is not finalized for removal. Despite these revisions, this measure is still duplicative in nature and less comprehensive as compared to measure Q260.
1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive:** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q259: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2). Measure Q259 is a more comprehensive measure accounting for the patient population found within measure Q347 as well as assessing for complications and appropriate length of stay.
N/A	352	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet.	American Association of Hip and Knee Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.8 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
NA	353	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant.	American Association of Hip and Knee Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.6 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are submitted to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is not furthering quality care, but simply submitting to a radiation dose index and does not deter excessive radiation. Despite this structure measure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement to require radiation reduction.
N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12 month period after the study.	American College of Radiology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this is not furthering quality care, but simply setting up a database. Despite this structure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0712e	371	CMS160 v8	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients 12 to 17 years of age and adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4 month period in which there was a qualifying depression encounter.	Minnesota Community Measurement	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure only captures the process of depression screening and is duplicative of previously finalized measure Q370: Depression Remission at Twelve Months. Measure Q370 is a more robust outcome measure, requiring depression remission for numerator compliance. The screening element found within this process measure is a part of logic for measure Q370. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to the clinician type: Pediatrics.
N/A	372	CMS82v7	eCQM Specifications	Process	Community/Population Health	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because denominator eligibility is determined by the visits to the child's MIPS eligible clinician. The quality action would not be attributed to the child's MIPS eligible clinician, but rather to the obstetrician or primary care provider of the mother. The measure does not account for instances where the mother is not present for the child's visits.
N/A	388	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy):** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy.	American Academy of Ophthalmology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.4 percent for the MIPS CQMs specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs specifications collection type is considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.9 percent for the Medicare Part B Claims specifications collection type and 98 percent for the MIPS CQMs specifications collection type. As such, the Medicare Part B Claims and MIPS CQMs specifications collection types are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 99.9 percent for the MIPS CQMs specifications collection type. As such, the MIPS CQMs specifications collection types are considered extremely topped out. The Medicare Part B Claims specification has not established a benchmark, but we do not maintain this collection type without a corresponding collection type. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end -stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measure initiative. There is limited adoption of the quality measure and does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. This concept would be more inclusive and better represented if the denominator was expanded to include patients with multiple chronic conditions.
N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Susceptible Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. Nafcillin, Oxacillin or Cefazolin) as definitive therapy.	Infectious Diseases Society of America	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.7 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: add criteria for denominator eligibility to include Diagnosis for Bacteremia (ICD-10-CM): R78.81 AND Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere (ICD-10-CM): B95.61. Despite these revisions offered by the measures steward, we do not believe this will affect the average performance for this measure.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission six months (+/- 60 days) after an index event date.	Minnesota Community Measurement	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this patient population and quality action are duplicative of previously finalized measure Q370: Depression Remission at Twelve Months but vary in timeframe in which depression remission is required. The extended timeframe allows assessment of patient to ensure management and prevention of depression relapse. American Psychiatric Association (2010) states "Continuation therapy is the four-to-nine month period beyond the acute treatment phase during which the patient is treated with antidepressants, psychotherapy, ECT or other somatic therapies to prevent relapse. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse." In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator allowing PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter. In addition, we propose to add this measure to the following specialty measure sets in the event the measure is retained in the MIPS program based on stakeholder comments within the program as it is clinically relevant to these clinician types: Pediatrics and Clinical Social Work. Despite these revisions offered by the measures steward, we prefer measure Q370 which supports the quality outcome depression remission at 12 months.
1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons	We propose the removal of this measure (finalized in (81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative in concept and patient population as the previously finalized measure Q258: Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7). Measure Q258 is a more comprehensive measure accounting for the patient population found within measure Q417 as well as assessing for complications and appropriate length of stay.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip.
0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistence of Beta-Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who were prescribed persistent beta-blocker treatment for six months after discharge.	National Committee for Quality Assurance	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the patient population is captured within previously finalized measure Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%). While the quality action requires persistent beta-blocker treatment, the performance period is narrowed to only include the patients hospitalized and discharged for the first 6 months of the performance period. This does not include patient hospitalized and discharged after July 1, thus missing a substantial portion of the patient population. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator exclusion adding advance illness and frailty. Despite these revisions offered by the measure steward, we maintain that measure Q007 will capture the patient population sampled within this measure and allows for a 12 month performance period.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0733	446	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Operative Mortality Stratified by the Five STS-EACTS Mortality Categories:** Percent of patients undergoing index pediatric and/or congenital heart surgery who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days (including patients transferred to other acute care facilities), and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, stratified by the five STAT Mortality Levels, a multi-institutional validated complexity stratification tool.	Society of Thoracic Surgeons	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the denominator has a very limited patient population. We believe this measure does not align with the meaningful measure initiative. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple program years suggests this is not an important clinical topic for MIPS eligible clinicians. In the event that the measure is retained in the MIPS program based on stakeholder comments, we propose to add this measure to the following specialty set as it is clinically relevant to this clinician type: Thoracic Surgery.
1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because clinically we believe this to be standard of care. The performance data does not support a meaningful gap. The average performance for this measure is 97.4 percent for the MIPS CQMs specifications collection type based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/342/2019%20MIPS%20Quality%20Benchmarks.zip. In the circumstance we do not finalize removal of this measure, we would maintain this measure with the following substantive change(s) based on the measure steward's input: update the denominator definition to align with current guidelines as referenced in Table D. 68: Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy of this document.
N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer with more than one emergency department visit in the last 30 days of life.	American Society of Clinical Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this may be outside of the eligible clinician's control. We believe previously finalized measure Q455: Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better) is a related concept that can be a better indicator of compassionate outcomes to the end of life care for oncology patients.

TABLE C: Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years

NQF # / eCQM NQF #	Quality #	CMS e-CQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died From Cancer Not Admitted to Hospice (lower score – better):** Percentage of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the concept would be captured in measure Q457: Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better) and is the more robust measure as it requires at least 3 days of hospice prior to death.
N/A	467	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Developmental Screening in the First Three Years of Life:** The percentage of children screened for risk of developmental, behavioral and social delays using a standardized screening tool in the 12 months preceding or on their first, second, or third birthday. This is a composite measure of screening in the first three years of life that includes three, age-specific indicators assessing whether children are screened in the 12 months preceding or on their first, second or third birthday.	Oregon Health & Science University	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program after review of denominator of this process measure is not able to specifically target a pediatric patients primary clinician for performance of developmental screening. The measure owner submitted a substantive change to revise the denominator eligible coding to include well-child visits. The well-child visit encounters would likely include the attestation of the numerator's quality action and therefore inflate performance of the measure. While we agree that screening pediatric patients for development milestones is indicative of quality interactions with patients, we believe that the complexity of implementing the proposed change creates a less meaningful assessment of MIPS eligible clinicians.
N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients aged 50 years and older who have had the Shingrix zoster (shingles) vaccination.	Centers for Medicare & Medicaid Services	We propose the removal of this measure (finalized in 83 FR 60108) as a quality measure from the MIPS program because it is duplicative of measure A.3: Adult Immunization Status proposed in this proposed rule. This new measure, if finalized, is a more robust immunization measure which requires multiple age-appropriate preventive immunizations. We are proposing to remove this measure to be consistent with ensuring measures are not duplicative and present an opportunity to provide a meaningful impact to quality.

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2022 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement period. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might be harmful for patients to receive a particular service when they should prioritize other services. The measure steward also believes that some of the services in this measure are not appropriate for patients 66 years of age and older who are living in a long-term institutional setting. We agree with the measure steward and believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

D.2. Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality #:	005
CMS eCQM ID:	CMS135v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**The measure title is revised to read:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD). **The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12- month period when seen in the outpatient setting OR at each hospital discharge **Updated denominator:** For the MIPS CQMs Specifications collection type for Submission Criteria 1 – "At least on additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters. **Updated numerator:** Added language for ARNI therapy. **Updated definition:** Added language for ARNI therapy.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	This measure already includes ARNI therapy in the specifications and coding as well as a statement about the fact that ARNIs are a numerator compliant clinical action. The measure is proposed to be globally updated to include ARNI therapy language in the title, description, numerator, definition, denominator exception, and rate aggregation to align with the intent of the measure. With the inclusion of ARNI therapy, the intent of this measure is aligned with the most current clinical guidelines for ACE/ARB therapies for patient's diagnoses with heart failure. Telehealth visits, for the additional denominator eligible encounters, were added for Submission Criteria 1 in the MIPS CQMs Specifications collection type.

D.3. Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality #:	007
CMS eCQM ID:	CMS145v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI or a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.
Substantive Change:	**Updated calculation method:** For the MIPS CQMs Specifications collection type: To be submitted as a single performance rate. **Updated denominator:** For the MIPS CQMs Specifications collection type, "At least one additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure performance calculation for the MIPS CQMs Specifications collection type so that it is submitted as a single performance rate as opposed to two performance rates. This change allows for better alignment between the collection types. We are also proposing to add telehealth visits for the additional denominator eligible encounters for the MIPS CQMs Specifications collection type. This change is in alignment with the eCQM Specifications collection type. We believe these changes will allow for data congruency between the collection types while also lessening burden for implementation of the measure across these collection types.

D.4. Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality #:	008
CMS eCQM ID:	CMS144v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**For the eCQM Specifications collection type:** The timing for cardiac pacer in situ diagnosis logic has been changed to 'overlaps after'. **Updated denominator: For the MIPS CQMs Specifications collection type**: For Submission Criteria 1, "At least one additional patient encounter during performance period", telehealth encounters will be included as denominator eligible encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type: the logic regarding the cardiac pacer in situ diagnosis is being proposed to be updated to change the timing to 'overlaps after' to ensure it is present at the time of the end of the encounter and for harmonization with CMS145v8. For the MIPS CQMs Specifications collection type: we propose to add telehealth encounters for the additional patient encounter as denominator eligible encounters for Submission Criteria 1. This change is in alignment with the eCQM Specifications collection type. We believe these changes will allow for data congruency between the collection types while also lessening burden for implementation of the measure across these collection types.

D.5. Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	009
CMS eCQM ID:	CMS128v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**Updated guidance:** Guidance statement updated to reflect the 105 day negative medication history. **Updated denominator:** The required visit needs to be in the 60 days before or after the initial patient population antidepressant medication dispensing event. The initial patient population dispensing period will be from May 1st of the year prior to the measurement period to April 30th of the measurement period. Added nursing home encounters to list of qualifying encounters. **Updated denominator exclusion:** Changed timing to 'overlaps' so that medications that are active in the 105 days prior may count.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to expand the denominator to include nursing home encounters as this measure is applicable to that setting and this will increase the number of MIPS eligible clinicians who can report on the measure. The required visit for the initial patient population is proposed to be in the 60 days before or after the initial patient population antidepressant medication dispensing event as the intent is for a physician who has influence over the medication choice and follow-up to report the measure. The measure steward feels, and we agree, that associating the visit with the medication dispensing event is more in line with the intent of the measure. The initial patient population dispensing period is also being updated. We are proposing to update the denominator exclusion logic so that medications that are active in the 105 days prior will also count as an exclusion. We are proposing to update the guidance as well to reflect the change in the denominator exclusion.

D.6. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	0089 / 0089e
Quality #:	019
CMS eCQM ID:	CMS142v8
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as the benchmarking data shows that this measure meets the extremely topped out definition, specifically for the Medicare Part B Claims Measure Specification collection type. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type and the MIPS CQMs Specifications collection type, as such, the measure will be retained for these two collection types.

D.7. Appropriate Testing for Children with Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	066
CMS eCQM ID:	CMS146v8
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Removed Ambulatory/ED grouping value set, instead using the individual value sets. **Updated denominator exclusions:** Added exclusion for competing diagnosis at the same encounter as the pharyngitis diagnosis or in the 3 days after the pharyngitis diagnosis.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM Specifications collection type: The Ambulatory/ED grouping value sets are proposed to be removed so that individual value sets will be used in order to increase transparency regarding which encounter value set is being utilized. A denominator exclusion for a competing diagnosis that occurs at the same encounter or 3 days after the pharyngitis diagnosis is proposed to be added to ensure the patient population being assessed is more in alignment with clinical intent of assessing whether or not children diagnosed with pharyngitis were correctly evaluated and subsequently ordered antibiotics.

D.8. Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections

Category	Description
NQF # / eCQM NQF #:	2726
Quality #:	076
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.
Substantive Change:	**Updated numerator definition:** Added definition for Hand Hygiene: Washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR).
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add the definition for hand hygiene that is found in the Clinical Recommendation Statement as a numerator definition to make it more prominent and add clarity for measure users.

D.9. Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients

Category	Description
NQF # / eCQM NQF #:	0389 / 0389e
Quality #:	102
CMS eCQM ID:	CMS129v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer. **Updated denominator:** Removed cryotherapy from denominator statement/header. **Updated denominator definition:** Removed "Note: Patients with multiple adverse factors may be shifted into the high/very high risk category" from definition of Intermediate Risk. **For the eCQM Specifications collection type:** removed SNOMED and CPT codes related to cryotherapy from the SNOMED CT extensional OID and CPT extensional OID "Prostate Cancer Treatment" value set.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to remove cryotherapy from the measure to align with updated clinical guidelines. Current clinical guidelines do not recommend cryotherapy as a routine primary therapy for localized prostate cancer due to the lack of long-term data comparing this to treatments such as radiation or radical prostatectomy. Given that the denominator includes treatments recommended for low/very low-risk prostate cancer patients, the measure steward's technical expert panel (TEP) agreed cryotherapy should be removed from the denominator. All coding related to cryotherapy is being removed in accordance with the updated guidelines. We are proposing to update the denominator definition to align with updated guidelines.

D.10. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	0104e
Quality #:	107
CMS eCQM ID:	CMS161v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.
Substantive Change:	**Updated denominator:** Added telehealth data element to "Major Depressive Disorder Encounter" definition using "Telehealth Services" value set. **Updated guidance:** Updated to reflect the inclusion of telehealth encounters. **Updated definition:** The specific type and magnitude of the suicide risk assessment is intended to be at the discretion of the individual clinician and should be specific to the needs of the patient. At a minimum, suicide risk assessment should evaluate: (1) Suicidal ideation (2) Patient's intent of initiating a suicide attempt AND, if either is present, (3) Patient plans for a suicide attempt (4) Whether the patient has means for completing suicide Low burden tools to track suicidal ideation and behavior such as the Columbia-Suicide Severity Rating Scale (C-SSRS) and the Suicide Assessment Five-Step Evaluation and Triage (SAFE-T) can also be used. Because no validated assessment tool or instrument fully meets the aforementioned requirements for the suicide risk assessment, individual tools or instruments have not been explicitly included in coding.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure was reviewed by PCPI's technical expert panel and it was recommended to include telehealth encounters. We are proposing to add telehealth data element to "Major Depressive Disorder Encounter" as telehealth encounters are directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We propose to reflect this change in the guidance header for additional clarity. We are proposing to add clarifying language in the definition header regarding suicide risk assessments that could be appropriate to meet the measure. It is still intended that the MIPS eligible clinician use their discretion when choosing the specific type and magnitude of the suicide risk assessment, based upon the patient's specific needs, but the suicide risk assessments should include, at minimum, certain criteria.

D.11. Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality #:	112
CMS eCQM ID:	CMS125v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.
Substantive Change:	**The measure description is revised to read:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period. **The numerator is revised to read:** Women with one or more mammograms 27 months prior to the end of the measurement period. **Updated denominator exclusions: For eCQM Specifications collection type:** (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator guidance: For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications collection types**: Added "This measure evaluates primary screening. Do not count biopsies, breast ultrasounds, or MRIs because they are not appropriate methods for primary breast cancer screening. Mammography screening is defined as a bilateral screening (both breasts) of breast tissue. If only one breast is present, unilateral screening (one side) must be performed on the remaining breast."
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add a timing component to the description for better clarity and alignment throughout the measure. The numerator was revised to state the timing in the same manner as the description, however, the timing itself has not been changed only stated differently. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. The measure steward also believes that some of the services in this measure are not appropriate for patients 66 years of age and older who are living in a long-term institutional setting. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. We are proposing to update the numerator guidance for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types to clarify the intent of the measure. The measure logic for the Medicare Part B Claims Measure Specifications will remain the same from prior years to allow a 27-month look back from the denominator eligible visit.

D.12. Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality #:	113
CMS eCQM ID:	CMS130v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients aged 66 years and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator guidance: For Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types:** Do not count DRE, FOBT tests performed in an office setting or performed on a sample collected via DRE.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, or who are living in a long-term institutional setting for more than 90 days. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. The measure steward believes the measure reflects services that may not be appropriate for patients in long-term institutional settings. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. We are also proposing to update guidance for numerator compliance for the Medicare Part B Claims Measure Specification and MIPS CQMs Specifications collection types to align with eCQM Specifications and CMS Web Interface Measure Specifications collection types. The update would not allow fecal occult blood test (FOBT) via tests performed in an office setting or performed on a sample collected via DRE to be numerator compliant. This update aligns with a more effective method as FOBT by stool passed spontaneously (SPS) appears to be statistically superior to FOBT by DRE. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.13. Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period. **Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator:** Allows use of a diagnosis of retinopathy as a proxy for a positive eye exam. • If the patient has a diagnosis of retinopathy that overlaps the measurement period, the patient will be required to have an eye exam in the measurement period. • If the patient does not have a diagnosis of retinopathy that overlaps the measurement period, the patient will be required to have an eye exam in the 24 months prior to the end of the measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure description to better align with proposed changes to logic. We agree with this update as it clarifies the intent of the measure. We are proposing to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, and for patients who are living in a long-term institutional setting, such as a nursing home. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services and that services within this measure may not be appropriate for older patients living in a long-term institutional setting for longer than 90 days during the measurement period. In response to reports from EHR vendors that the measure was not reportable due to the results from an eye exam not being in structured data, we are proposing to use the diagnosis of retinopathy as a proxy for a positive eye exam. Patients with a diagnosis of retinopathy are required to have an eye exam yearly while patients without that diagnosis are required to have an eye exam once every 24 months. We believe that by removing these two patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

D.14. Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality #:	119
CMS eCQM ID:	CMS134v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older with advanced illness and frailty. (2) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. **For CQMs Specifications collection type:** Added the following: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (3) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (4) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add denominator exclusions for patients aged 66 years and older with advanced illness and frailty, taking certain dementia medications, and for patients who are living in a long-term institutional setting, such as a nursing home. The measure steward believes it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services and that services within this measure may not be appropriate for older patients living in a long-term institutional setting for longer than 90 days during the measurement period. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians.

D.15. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0421 / 0421e
Quality #:	128
CMS eCQM ID:	CMS69v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous twelve months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous twelve months of the current encounter. Normal Parameters: Age 18 years and older BMI $\geq$ 18.5 and $<$ 25 kg/m^2.
Substantive Change:	**Updated denominator exclusions:** Added patients in hospice care. Removed "or refuse follow-up" language from denominator exclusion. **For the eCQM Specifications collection type:** Added a 'union' operator of 'Intervention, Performed' for each 'Intervention, Order' for Above and Below Normal Follow-Up Interventions, and a 'union' operator of 'Intervention, Not Performed' for each 'Intervention, Not Ordered' for Above and Below Normal Follow-up Interventions not done due to a medical reason.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward convened an expert work group (EWG) and it was recommended that patients receiving hospice care should be removed from this measure. We agree with the EWG that this patient population should be removed as patients in hospice care would not benefit from this clinical service. Since assessment of BMI is not a valuable clinical assessment for hospice patients we believe that by removing this patient population it will reduce the burden of submission for these MIPS eligible clinicians providing care to these patients. We are proposing to remove "or refuse follow-up" from the denominator exclusion for clarity. We are proposing to add a union operator to the eCQM Specifications collection type to allow the intervention to be either completed or ordered, creating a new numerator option. We propose to update the eCQM Specifications collection type by adding a 'union' operator to allow intervention to be either completed or ordered for numerator compliance. This allows for better alignment with measure intent.

D.16. Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0418 / 0418e
Quality #:	134
CMS eCQM ID:	CMS2v9
National Quality Strategy Domain:	Community/ Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **Updated denominator:** Added speech language pathology MIPS eligible clinician type. **For the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications:** Added physical therapy MIPS eligible clinician type. **Updated denominator exception:** Updated language to situations where the patient's cognitive capacity, functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment. **The numerator is revised to read:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **For the eCQM Specifications collection type:** Updated the "Depression medications – adolescent" and the "Additional evaluation for depression – adolescent" value sets to include additional medications.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure description for better alignment with the measure intent and clinical practices, therefore the measure, will reflect those changes within the guidance and logic. This change will not affect the denominator population, but may expand the numerator population and provides a better opportunity for compliance. Based upon requests from stakeholders physical therapy evaluation codes are proposed to be add to the denominator eligible encounters to allow for this measure to be used in an additional setting. We agree that this is a clinically relevant measure to the physical therapy setting. We are proposing to update the denominator exception for better clarity to allow MIPS eligible clinicians to use cognitive capacity as a denominator exception. The measure steward based this decision on feedback from clinical subject matter experts. We agree that this is not a new denominator exception, but rather clarifies what is deemed a denominator exception for this measure. The eCQM Specifications collection type's adolescent medication value sets is proposed to be updated to include additional medications based upon recommendations from clinical subject matter experts. The additions will provide an opportunity for better compliance by expanding the list of appropriate medication codes while also improving alignment with measure intent.

D.17. Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384/0384e
Quality #:	143
CMS eCQM ID:	CMS157v8
National Quality Strategy Domain:	Person and Caregiver Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated Guidance: For the eCQM Specifications collection type:** This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face interaction. Due to the nature of some applicable coding related to the radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy within 30 days prior to the encounter AND administered chemotherapy within 30 days after the date of the encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the guidance within the eCQM Specifications collection type to address the limitations of the radiation treatment management code 77427 and to provide clarification about the variation in how this code is applied versus how the measure performance is assessed.

D.18. Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain

Category	Description
NQF # / eCQM NQF #:	0383
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.
Substantive Change:	**Updated the description to read**: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain. **Updated the denominator to read:** All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **Updated the numerator to read:** Patient visits that included a documented plan of care to address pain
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revert this measure to the 2018 performance period measure specification. The 2019 measure narrows the patient population to those who report moderate to severe pain and require the plan of care before or on the data of the second visit with the clinician. The measure steward has submitted this version to NQF for re-endorsement where the measure steward received feedback to further test the updated analytics. As such, we agree with reverting to the NQF-endorsed measure. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.19. Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).
Substantive Change:	**Updated definition:** Biologic DMARD Therapy- Includes Abatacept (Orencia), Adalimumab (Humira), Adalimumab-adbm (Cyltezo), Adalimumab-atto (Amjevita), Anakinra (Kineret), Baricitinib (Olumiant), Certolizumab pegol (Cimzia), Etanercept (Enbrel), Etanercept-szzs (Erelzi), Golimumab (Simponi), Infliximab (Remicade), Infliximab-abda (Renflexis), Infliximab-dyyb (Inflectra), Infliximab-qbtx (Ixifi), Sarilumab (Kevzara), Tocilizumab (Actemra), Tofacitinib (Xeljanz).
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add Baricitinib (olumiant) and remove Rituximab (Rituxan) to the definition of "Biologic DMARD Therapy" as it was approved in 2018 by the FDA for the treatment of rheumatoid arthritis. We agree with the inclusion of Baricitinib in order to capture the relevant patient population. This revision allows eligible clinicians to achieve performance with use of a new pharmacological therapy to treat RA.

D.20. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**Updated description:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year. **Updated definition:** Removed Patient Activity Scale (PAS) from definition of "Assessment of Disease Activity".
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward recently conducted an assessment of available RA disease activity tools and is updating the list of tools they will endorse. The Patient Activity Scale (PAS) will no longer be an ACR-preferred rheumatoid arthritis disease activity measurement tool and as such, we are proposing to remove this scale as an acceptable assessment tool within this measure and update the description to align with this revision.

D.21. Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months. **The numerator is revised to read:** Patients who have been assessed for glucocorticoid use and for those on prolonged doses of prednisone >5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of a glucocorticoid management plan within 12 months.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that this measure be revised to expand the numerator population being assessed for improvement or no change in disease activity by dropping the prolonged doses of prednisone from ≥ 10 mg daily (or equivalent) to > 5 mg daily (or equivalent). The measure steward conducted literature review that found a nearly 2-fold greater serious infection at 5-10 mg of prednisone in RA. This change takes into consideration the dangers to patients associated with being on 5-10 mg doses of prednisone. We agree with the decision to drop the dosage of prednisone to > 5 mg daily (or equivalent) given it aligns more closely to dosing associated with patient risk and it is important to include these patients in the population being assessed for improvement or no change.

D.22. Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator:** Added physical and occupational therapy, ophthalmology, audiology and speech language pathology MIPS eligible clinician types.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing, based upon requests from stakeholders, that coding be added to the denominator eligible encounters to include physical/occupational therapy, ophthalmology, audiology and speech language pathology MIPS eligible clinician types. This expansion of the numerator allows this measure to be used in an additional setting. We agree that this measure is clinically relevant for the physical therapy setting.

D.23. Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	2624
Quality #:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Updated denominator:** Added mental/behavioral health, audiology, and speech language pathology MIPS eligible clinicians.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the denominator be expanded to include coding for more MIPS eligible clinicians. We agree with the decision to expand the MIPS eligible clinician types as it is clinically relevant to this clinician type and allows for the removal of duplicative quality measures promoting functional assessment.

D.24. Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality #:	191
CMS eCQM ID:	CMS133v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery.
Substantive Change:	**The measure description is revised to read:** Percentage of cataract surgeries for patients aged 18 and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery. **The initial population is revised to read: For the eCQM Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** All cataract surgeries for patients aged 18 years and older who did not meet any exclusion criteria. **The denominator exclusion is revised to read:** Cataract surgeries in patients with significant ocular conditions impacting the visual outcome of surgery. **Update denominator exclusions:** Removed the following data elements/value sets: 'Chorioretinal Scars,' 'Moderate or Severe Impairment, Better Eye, Profound Impairment, Lesser Eye,' 'Other Corneal Deformities,' 'Other Disorders of Sclera,' 'Other Retinal Disorders,' and 'Profound Impairment, Both Eyes'. Add the following data elements/value sets: 'Cataract, Congenital,' 'Cataract, Mature or Hypermature,' 'Cataract, Posterior Polar,' 'Hypotony of Eye,' 'Macular Scar of Posterior Polar' (new value set), 'Morgagnian Cataract,' 'Posterior Lenticonus,' 'Retrolental Fibroplasias,' 'Traumatic Cataract,' and 'Vascular Disorders of Iris and Ciliary Body'. **The numerator is revised to read:** Cataract surgeries with best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following cataract surgery.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing that the measure language be updated to reflect that it is not a patient-based measure, but rather a measure that assesses cataract surgeries. The measure steward believes and we agree this update in language better aligns to the measure intent and implementation and also aligns with the current measure guidance. The measure steward convened an Eye Care technical expert panel (TEP) who also agreed that these language updates would provide more clarity around the intent, and be more explicit. The Eye Care TEP also reviewed and evaluated the denominator exclusions resulting in removal and addition of data elements/value sets outlined above.

D.25. Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	0422
Quality #:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the knee impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the knee and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a knee impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1009) identifying the close of a Treatment Episode for the same knee deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional knee deficit, progressing through treatment without interruption (for example a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a knee deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with knee impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. The numerator is revised to read: Patients who were presented with the Knee FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.26. Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	0423
Quality #:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the hip impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the hip and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a hip impairment, who has had an interruption of a Treatment Episode for the same functional hip deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1010) identifying the close of a Treatment Episode for the same hip deficit identified at Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional hip deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a hip deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with hip impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care no indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery.). (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read**: Patients who were presented with the Hip FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.27. Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / ECQM NQF #:	0424
Quality #:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot, or ankle impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the lower leg, foot or ankle and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a lower leg, foot or ankle impairment, who has had an interruption of a Treatment Episode for the same functional lower leg, foot or ankle deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1011) identifying the close of a Treatment Episode for the same lower leg, foot or ankle deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional lower leg, foot or ankle deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a foot, ankle or lower leg deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with foot, ankle or lower leg impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care no indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Foot/Ankle FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

Category	Description
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.28. Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / ECQM NQF #:	0425
Quality #:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the low back impairment successfully calculated and the score was less than zero (< 0)" will become Performance Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the low back and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a low back impairment, who has had an interruption of a Treatment Episode for the same functional low back deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1012) identifying the close of a Treatment Episode for the same low back deficit identified at Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a Discharge from the current Treatment Episode Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional low back deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a low back functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with a low back impairment who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. The numerator is revised to read: Patients who were presented with the Low Back FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.29. Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / ECQM NQF #:	0426
Quality #:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the shoulder impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the shoulder and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with a shoulder impairment, who has had an interruption of a Treatment Episode for the same functional shoulder deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1013) identifying the close of a Treatment Episode for the same shoulder deficit identified at the Initial Evaluation and documented by a discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional shoulder deficit, progressing through treatment, without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for a shoulder functional deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with shoulder impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Shoulder FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it creates a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.30. Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / ECQM NQF #:	0427
Quality #:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**Updated numerator:** Changed to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change. Numerator option "Risk-Adjusted Functional Status Change Residual Score for the elbow, wrist, or hand impairment successfully calculated and the score was less than zero (< 0)" will become Performance Not Met. **Updated definitions:** Removed: (1) Admission (Option 1 & 2) (2) Admission (Option 3 & 4) (3) Discharge (Option 1 & 2) (4) Discharge (Option 3 &4) Added: (1) Initial Evaluation: An Initial Evaluation is the first encounter for a functional deficit involving the elbow, wrist, or hand and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code. A patient presenting with an elbow, wrist, or hand impairment, who has had an interruption of a Treatment Episode for the same functional knee deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. (2) Discharge: Discharge is accompanied by a treatment finalization and evaluation completion M-Code (M1014) for identifying the close of a Treatment Episode for the same elbow, wrist or hand deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. Updated: Treatment Episode: A Treatment Episode is defined as beginning with an Initial Evaluation for a functional elbow, wrist or hand deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge, signifying that the treatment has been completed. A patient currently under clinical care for an elbow, wrist or hand deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Updated denominator:** Consolidated all options into one denominator criteria. **The denominator is revised to read**: All patients 14 years and older with elbow, wrist or hand impairments who have initiated a Treatment Episode. **Updated denominator exclusions:** Added the following: (1) Patients with diagnosis of a degenerative neurological condition such as ALS, MS, Parkinson's diagnosed at any time before or during the episode of care. **Updated denominator exceptions:** Added the following: (1) Ongoing care not indicated, patient self-discharged early and seen only 1-2 visits (e.g., financial or insurance reasons, transportation problems, or reason unknown). (2) Ongoing care not indicated, patient discharged after only 1-2 visits due to specific medical events, documented in the medical record that make the treatment episode impossible such as the patient becomes hospitalized or scheduled for surgery. (3) Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Moved from denominator exclusion to denominator exception (1) Patient refused to participate. **The numerator is revised to read:** Patients who were presented with the Elbow/Wrist/Hand FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score.

Category	Description
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing the numerator be updated to define Performance Met as meeting or exceeding the risk adjusted prediction of functional status change, making a score of less zero non-compliant and thus a Performance Not Met. We agree with this change and believe it will create a more robust outcome measure as it is looking for a meets or exceeds. The denominator exclusions and exceptions are being updated with clinically relevant reasons for exclusion from the denominator or the performance rate. The current denominator exclusions are being moved to denominator exceptions as this aligns better with the measure workflow. In addition, we propose to consolidate the denominator options 1, 2, 3, and 4 into one denominator criteria for ease of use. The denominator definitions, denominator, and numerator are being updated to align with these changes. We agree with these changes as they make implementation of the measure less burdensome for the clinician. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.31. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / ECQM NQF #:	0028 / 0028e
Quality #:	226
CMS eCQM ID:	CMS138v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user. **Updated denominator: For the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types:** Added physical therapy MIPS eligible clinician type. **Updated Guidance: For the Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types:** Added: (1) The denominator of population criteria 2 is a subset of the resulting numerator for population criteria 1, as population criteria 2 is limited to assessing if patients identified as tobacco users received an appropriate tobacco cessation intervention. For all patients, population criteria 1 and 3 are applicable, but population criteria 2 will only be applicable for those patients who are identified as tobacco users. Therefore, data for every patient that meets the initial population criteria will only be submitted for population 1 and 3, whereas data submitted for population 2 will be for a subset of patients who meet the initial population criteria, as the denominator has been further limited to those who were identified as tobacco users. (2) To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the 24-month period. If a patient has multiple tobacco use screenings during the 24-month period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. **Updated instructions: For the MIPS CQM Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. For this implementation of the measure, the 24 month look back period includes the program year and the year prior. For Quality Payment Program (QPP) 2020, the 24 month period would be from 1/1/2019-12/31/2020. **Updated guidance: For the CMS Web Interface Measure Specifications collection types:** • If there is more than 1 patient query regarding tobacco use, use the most recent query during the 24-month period to determine tobacco status. • "Within 24 months" is defined as the 24-month look-back from the measurement period end date (1/1/2019 - 12/31/2020). • Screening for tobacco use may be completed during a telehealth encounter. • Tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. • Screening for tobacco use and cessation intervention do not have to occur on the same encounter, but both must occur during the 24-month look-back period. • Screening for tobacco use and cessation intervention may be completed during a telehealth encounter. • Tobacco cessation intervention may be completed during a telehealth encounter.

Category	Description
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the measure description be revised to clarify the summarized intent for population criteria 2. Based upon requests from stakeholders, physical therapy evaluation codes are also being proposed for addition in the denominator eligible encounters for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection types to allow for this measure to be used in an additional setting. We agree that this preventive assessment is a clinically relevant measure for clinicians in the physical therapy setting. We are proposing refinements to the guidance for the Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications collection types in response to stakeholder feedback regarding the timing for which tobacco cessation intervention must occur. In response to our determination and stakeholder feedback for the CMS Web Interface Measure Specifications, Medicare Part B Claims Measure Specifications, and MIPS CQMs Specifications collection types, we are proposing to allow a 24-month period to assess for tobacco cessation intervention. These refinements are in alignment with the clinical guidelines and will decrease burden for eligible clinicians performing tobacco screening and tobacco cessation intervention. The timing refinement proposed will maintain the balance of clinical guideline and measure alignment, and support our effort to reduce burden for measure submission. Additionally, this timing refinement allows the clinician to create personalized, patient-centered care while still maintaining the clinical integrity of the measure and clinical guidelines. The CMS Web Interface Measure Specifications collection type was updated with additional guidance in order to add clarity regarding how this measure is implemented using that collection type. We are also proposing updates to the instructions for MIPS CQMs Specifications collection types to further clarify the timing of the tobacco cessation intervention in alignment with the updated numerator guidance. We agree this proposal will maintain clinical intent, provide clarity, reduce clinician burden, and allow for personalized patient care. We are also proposing updates to guidance for the Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications collection types based upon stakeholder feedback requesting clarification regarding interpretation of the three rates included in this measure.

D.32. Controlling High Blood Pressure

Category	Description
NQF # / ECQM NQF #:	0018 / N/A
Quality #:	236
CMS eCQM ID:	CMS165v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Updated denominator: For the eCQM Specifications collection type:** Removed Blood Pressure Visit grouping value set and added in the individual value sets. **Updated denominator exclusions: For eCQM Specifications collection type:** Added the following: (1) Patients 66 years of age and older who are living in a long-term institutional setting, such as a nursing home, for more than 90 days in the measurement period. (2) Patients 66 year of age and older with advanced illness and frailty. **For Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, and MIPS CQMs Specifications collection type:** Updated: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. Added: (1) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (3) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine **Updated numerator/guidance:** Updated to allow blood pressures taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (i.e. patient's domicile) to count towards the measure with additional clarification regarding usable blood pressure readings: -Not requiring the numerator blood pressure reading to be during a visit or overlap with a diagnosis of hypertension. (Applicable to eCQM only). -If the day of the last blood pressure reading there are multiple blood pressure readings on that day, use the lowest systolic and diastolic on that day. -The blood pressure reading that is being used should not come from an ED or inpatient visit. -Do not include blood pressure readings reported by or taken by the patient.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome

Rationale:	We are proposing for the eCQM specifications collection type: In order to increase transparency of which value set is being used for encounters, the "Blood Pressure Visit" grouping value set is being removed so that individual value sets will be used. We are proposing to update the allowable denominator exclusions to include patients 66 years of age and older with advanced illness and frailty, patients with dementia taking the listed medications, and patients who are living in a long-term institutional setting, such as a nursing home, for more than 90 days during the measurement period. The measure steward believes and we agree it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might be harmful for patients to receive a particular service when they should prioritize other services. Additionally, we believe that some of the services in this measure are not appropriate for patients who are living in a long-term institutional setting for more than 90 days during the measurement period. We believe that by removing these patient populations, the burden to submit data is lessened for these MIPS eligible clinicians. Additionally, we propose the measure guidance be updated to align with the 2018 measure guideline updates making it so that a visit is no longer required for the numerator blood pressure reading with additional guidance that blood pressure should not be taken during major events as this can artificially elevate blood pressure. In alignment with this, blood pressure readings from an ED or inpatient visit should not be used as a numerator blood pressure reading. The guidance is also being updated to allow blood pressure readings taken by a clinician from remote monitoring devices in a medical setting or in an offsite setting (i.e. patient's domicile) to be numerator compliant. Patient reported blood pressure readings cannot be used for numerator compliance.

D.33. Use of High-Risk Medications in the Elderly

Category	**Description**
NQF # / ECQM NQF #:	0022 / N/A
Quality #:	238
CMS eCQM ID:	CMS156v8
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. (1) Percentage of patients who were ordered at least one high-risk medication. (2) Percentage of patients who were ordered at least two of the same high-risk medications.
Substantive Change:	**Updated numerator statement for submission criteria 2:** Percentage of patients who were ordered at least two of the same high-risk medications on different days. **Updated guidance:** Added 'on different days' to align with update to numerator submission criteria 2.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The numerator statement for submission criteria 2 is proposed to be updated to clarify that the assessment is looking for high-risk medications that are prescribed on different days, which is in alignment with the intent of the assessment being captured. This update is also reflected in the guidance.

D.34. Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	240
CMS eCQM ID:	CMS117v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday
Substantive Change:	**The measure description is revised to read:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. **Updated numerator:** Added value set for Hepatitis B carriers to allow Hepatitis B carriers to meet this part of the numerator. **Updated definition:** Removed 'Three HiB Vaccinations' and added new definition statements 'HiB 3 Dose Immunizations or Procedures,' 'HiB 4 Dose Immunizations or Procedures,' 'HiB 3 or 4 Dose Immunizations,' 'All HiB Vaccinations,' and 'Has Appropriate Number of HiB Immunizations.' Revised logic to include the correct number of HiB doses depending on the manufacturer of the vaccine given to align with current guidelines. Updated the logic for the HiB vaccine to require the correct amount of doses depending on the manufacturer of the vaccine given. Create a 3 dose and a 4 dose HiB vaccine.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the numerator be updated to include a value set for Hepatitis B carriers in order to allow this patient population to meet Hep B vaccine numerator compliance piece. We agree that this would suffice for the "had documented history of the illness" piece of numerator compliance. Additionally, we propose that the measure logic be updated for the HiB vaccine to ensure the correct dosing is administered as instructed by the drug manufacturer's instructions and alignment with the current guidelines. The description is also being updated to align with this. We agree the logic should match the dosing of the vaccine given to ensure that the patient is receiving the correct and full dosage.

D.35. Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
NQF # / eCQM NQF #:	0643
Quality #:	243
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator exceptions:** Added (1) Documentation of patient reason(s) for not referring to an outpatient CR program (for example, no traditional CR program available to the patient, within 60 min [travel time] from the patient's home, patient does not have access to an alternative model of CR delivery that meets all criteria for a CR program, patient refused or other patient reasons).
Steward:	American Heart Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing a new denominator exception be added to allow for documentation of patient reason(s) for not having a CR referral. The measure stewards believes denominator exceptions are used in select cases to allow for a fairer measurement of quality for those providers with higher risk populations. Exceptions are also used to defer to the clinical judgment of the provider. A MIPS eligible clinician who recommends CR referral to an eligible patient whom then refuses at the time of referral for one or more reasons (for example, lack of transportation, patient preference), will now be able to exclude this patient from the numerator population. In such a case, the MIPS eligible clinician will not be penalized based upon patient reason(s) for not having a CR referral. If the patient has told the physician that he/she does not wish to enroll in a CR program, the MIPS eligible clinician can document in the medical record that he/she has recommended referral but that the patient has refused CR. The measure steward believes this is important because, in this scenario, the MIPS eligible clinician should not be penalized for the lack of a completed CR program referral as long as the CR referral recommendation and the patient refusal are documented. By adding this exception, reasons for patient non-compliance can be better tracked to correspond with implementing practices that may improve compliance and thereby overall clinical care.

D.36. Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	268
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.
Substantive Change:	**The measure description is revised to read:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy. **Updated denominator:** All females aged 12 years and older with a diagnosis of epilepsy. **Updated numerator:** Female patients or caregivers counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy **Updated denominator exceptions:** Removed (1) Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy (4340F with 1P) **Updated definition of "Counseling"** - Counseling must include a discussion of at least two of the following three counseling topics: • Need for folic acid supplementation, • Drug to drug interactions with contraception medication, • Potential anti-seizure medications effect(s) on fetal/child development and/or pregnancy.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the denominator be expanded to include all females aged 12 years and older and that the denominator exception of "Documentation of medical reason(s) why counseling was not performed for women of childbearing potential with epilepsy" be removed as there is no longer an exception for patients with a diagnosis of neurodevelopmental disorder, encephalopathy, hydrocephalus, brain injury, cerebral palsy, severe cognitive impairment, or severe intellectual disability. The description is being updated to reflect the changes made to the denominator. The numerator action was updated to require counseling for both contraception and pregnancy in relation to epilepsy and how its treatment may affect. We agree with this requirement as both clinical aspects are important to the patient. The measure steward has requested, and we agree with, the denominator expansion and the removal of the denominator exception as they believe all women diagnosed with epilepsy at risk for pregnancy and/or pregnancy complications should be counseled.

D.37. Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	283
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Substantive Change:	**Update denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing that the denominator coding be expanded to include physical therapy as a denominator eligible encounter. We agree with the decision to expand this measure to physical therapy MIPS eligible clinicians as it is clinically relevant to this clinician type.

D.38. Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	286
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**Updated denominator:** Added physical therapy MIPS eligible clinician type.
Steward:	American Psychiatric Association and American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the denominator coding be expanded to include physical therapy as a denominator eligible encounter. We agree with the decision to expand this measure to physical therapy MIPS eligible clinicians as it is clinically relevant to this clinician type.

D.39. Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.
Substantive Change:	**Updated numerator options:** Performance Met: Psychosis, depression, anxiety, apathy, AND impulse control disorder assessed Performance Not Met: Psychosis, depression, anxiety, apathy, AND impulse control disorder not assessed
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the numerator options to better align with the intent of the measure, which requires assessment of five individual components of psychiatric symptoms. We agree with the measure steward that this update to the numerator options aligns with the intent of the measure.

D.40. Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	305
CMS eCQM ID:	CMS137v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.
Substantive Change:	**The measure description is revised to read:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention. **Updated initial population:** Changed intake period for the initial population to January 1 to November 14. Added telehealth services to initial population encounter value sets. **Updated numerator:** Added telehealth services to the numerator encounter value sets. Added Opiate Antagonists for numerator compliance **Numerator 1 is revised to read:** Initiation of treatment includes either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. **Numerator 2 is revised to read:** Engagement in ongoing treatment includes two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention (i.e., engagement for these members cannot be satisfied with medication treatment alone).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the initial population and numerator value sets be updated to include telehealth services. We agree with including telehealth services as they are appropriate for this measure and patients using these services should be included in the initial population as well as be considered for numerator compliance. Both numerators are being updated to add pharmacotherapy as a numerator compliant clinical quality action. Numerator 2 is also being updated to reflect the change in the time period for follow-up, which is increasing to 34 days from 30 days and to align with pharmacotherapy addition; patients who initiated treatment with a medication need two or more engagement events where only one can be a medication treatment event.

D.41. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	317
CMS eCQM ID:	CMS22v8
National Quality Strategy Domain:	Community /Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Updated logic to allow for the documentation of a reason (finding of elevated blood pressure or hypertension) for scheduling a follow up visit and added value set "Finding of Elevated Blood Pressure or Hypertension". Added Potassium and Sodium codes to the Dietary Recommendation value set. **Updated numerator definition:** Added potassium and sodium for dietary/lifestyle recommendations.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the logic to allow for the documentation of a reason (finding of elevated blood pressure or hypertension) for scheduling a follow up visit which improves alignment with measure intent. This logic change will include the addition of a new values set "Finding of Elevated Blood Pressure or Hypertension" strengthening alignment with measure intent. We also propose to add clinically relevant potassium and sodium codes to expand documentation options that align with the measure intent. This will also be reflected in the numerator definition.

D.42. Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525
Quality #:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Updated denominator:** Removed emergency medicine setting.
Steward:	American College of Cardiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose and agree with the measure steward's request to remove the emergency department setting. Chronic anticoagulation therapy would be managed by a clinician providing continuous medical care which would not be applicable to the emergency medicine specialty.

D.43. Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	332
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Substantive Change:	**Updated denominator:** Changed requirements for denominator eligibility Patients aged ≥ 18 years on date of encounter AND **Diagnosis for bacterial and infectious agent** **OR** **Sinusitis caused by, or presumed to be caused by, bacterial infection** AND Patient encounter WITHOUT Telehealth Modifier AND Antibiotic regiment prescribed
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing the measure no longer requires a diagnosis for bacterial and infectious agent to be denominator eligible as long as the sinusitis is caused by, or presumed to be caused by, bacterial infection. We agree that this change will not change the intent of the measure, but could lessen the burden to MIPS eligible clinicians by removing the requirement for a diagnosis.

D.44. Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.
Substantive Change:	**The measure title is revised from Elective Delivery or Early Induction Without Medical Indication ≥ 37 and < 39 Weeks (Overuse) to read:** Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse). **The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. **Updated denominator:** Changed to include all deliveries at < 39 weeks of gestation. **Updated numerator:** Numerator options will be updated to reflect the measure now including all deliveries at < 39 weeks gestation.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing the measure population be expanded to include all deliveries at < 39 weeks of gestation. We agree with this change as delivery prior to 39 weeks of gestation increases risk to both the mother and baby. Induction prior to 39 weeks of gestation should only be performed when clinically indicated. It is important to have a complete population to ensure that all instances of early induction are being captured and assessed for proper clinical action.

D.45. Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, and family and contraceptive planning.
Substantive Change:	**Updated description to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **Updated numerator:** Added clinical actions necessary for numerator compliance (1) Tobacco use screening and cessation education (2) Healthy lifestyle behavioral advice to bring the BMI within healthy limits (3) Immunization review and education
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	Three more components have been added to the list of clinical actions needed at a post-partum visit in order to be numerator compliant. The measure steward convened an expert work group (EWG) who, upon literature review, recommended adding these three clinical activities. The description was updated to align with the additional clinical actions. We agree and propose that that these clinical actions should be included in a post-partum visit as they will positively impact patient health and are clinically valuable in supporting post-partum patients.

D.46. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test. **The numerator is revised to read:** Patients who have a documented negative TB screening or have documentation of the management of a positive TB screening test with no evidence of active tuberculosis, confirmed through use of radiographic imaging (i.e., chest x-ray, CT) prior to treatment with a biologic immune response modifier.
Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	Newly published psoriasis clinical guidelines recommend that tuberculosis (TB) screening tests be completed prior to treatment. Numerator compliance for this measure will now have a timing component associated with the TB screening tests and imaging as they need to be completed prior to treatment with a biologic immune response modifier. We agree and propose this change as it follows the current clinical guidelines.

D.47. Pain Brought Under Control Within 48 Hours

Category	Description
NQF # / eCQM NQF #:	0209
Quality #:	342
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.
Substantive Change:	**Updated denominator:** Added the outpatient setting.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing that the denominator coding be expanded to include the outpatient setting as an applicable setting. We received prior stakeholder feedback with this request and agree with the decision to expand this measure to the outpatient MIPS eligible clinicians as it is clinically relevant to this setting.

D.48. HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	348
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.
Substantive Change:	**The measure title is revised from HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate to read:** Implantable Cardioverter-Defibrillator (ICD) Complications Rate.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.

D.49. Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality #:	370
CMS eCQM ID:	CMS159v8
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated denominator:** Allow PHQ-9/PHQ9M to be administered during the index encounter or up to 7 days prior to encounter.
Steward:	Minnesota Community Measurement
High Priority Measure:	No
Measure Type:	Outcome
Rationale:	The measure steward believes that allowing flexibility for the timeframe in which a PHQ-9/PHQ-9M can be obtained will accommodate pre-visit planning or distribution of a PHQ-9/PHQ-9M tool prior to the encounter (office visit, psychiatry or psychotherapy visit, telephone or online encounter). The intent of this change includes the following principles: (1) The patient must have the corresponding diagnosis at the time of the index encounter. (2) The patient must have completed the PHQ-9/PHQ-9M and have a score greater than 9. (3) That same PHQ-9/PHQ-9M is directly tied to and used during the index encounter. We agree and propose this change as it will allow for pre-visit planning and administration of the tool while also accounting for clinical workflow. Additionally, this revision may lessen the burden of completing the PHQ-9/PHQ-9M tool during the health visit.

D.50. Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	377
CMS eCQM ID:	CMS90v9
National Quality Strategy Domain:	Person and Caregiver- Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated numerator:** Added the Minnesota Living with Heart Failure Questionnaire (MLHQF) tool and the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) tool to the list of acceptable FSAs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The Minnesota Living with Heart Failure Questionnaire (MLHQF) tool and the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) tool are proposed to be added to the list of numerator compliant tools that may be used to complete the measure's clinical action. The MLHQF tool has previously been approved by the measure steward's expert work group for inclusion in this measure and the KCCQ-12 tool is being included based upon expert feedback and stakeholder requests, as the measure already contains the KCCQ tool. We agree and are proposing that both of these tools are relevant and appropriate for inclusion in this measure and, potentially, will capture an increased number of instances that meet numerator requirements.

D.51. Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	378
CMS eCQM ID:	CMS75v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The numerator is revised to read:** Children who had cavities or decayed teeth overlapping the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the numerator statement to include a timing component for better alignment with numerator logic.

D.52. Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	379
CMS eCQM ID:	CMS74v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The numerator is revised to read:** Children who receive a fluoride varnish application during the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the numerator header to align with the numerator logic.

D.53. Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	1365e
Quality #:	382
CMS eCQM ID:	CMS177v8
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.
Substantive Change:	**Updated numerator:** Added telehealth data element to "Major Depressive Disorder Encounter" definition using "Telehealth Services" value set (OID: 2.16.840.1.113883.3.464.1003.101.12.1031). **Updated guidance:** A suicide risk assessment should be performed at every visit for major depressive disorder during the measurement period. This measure is an episode-of-care measure; the level of analysis for this measure is every visit for major depressive disorder during the measurement period. For example, at every visit for MDD, the patient should have a suicide risk assessment. Use of a standardized tool(s) or instrument(s) to assess suicide risk will meet numerator performance, so long as the minimum criteria noted above is evaluated. Standardized tools can be mapped to the concept "Intervention, Performed": "Suicide risk assessment (procedure)" included in the numerator logic below, as no individual suicide risk assessment tool or instrument would satisfy the requirements alone. **Updated numerator definition:** The specific type and magnitude of the suicide risk assessment is intended to be at the discretion of the individual clinician and should be specific to the needs of the patient. At a minimum, suicide risk assessment should evaluate: (1) Risk (for example, age, sex, stressors, comorbid conditions, hopelessness, impulsivity) and protective factors (for example, religious belief, concern not to hurt family) that may influence the desire to attempt suicide. (2) Current severity of suicidality. (3) Most severe point of suicidality in episode and lifetime. Low burden tools to track suicidal ideation and behavior such as the Columbia-Suicidal Severity Rating Scale can also be used. Because no validated assessment tool or instrument fully meets the aforementioned requirements for the suicide risk assessment, individual tools or instruments have not been explicitly included in coding.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The measure steward's Technical Expert Panel (TEP) recommended adding telehealth services to the numerator eligible encounters. We agree and propose that performing suicide risk assessments is a clinically relevant action that should be completed by MIPS eligible clinicians providing telehealth services for patients diagnosed with major depressive disorder. It is important for patient safety that this clinical action is being performed on all patients with this diagnosis regardless of setting. The guidance and numerator definition are being updated per TEP recommendations to clarify that while sample assessments are listed, they are not reflected in the coding of this measure because the assessments do not meet all of the requirements for the suicide risk assessment.

D.54. Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	385
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.
Substantive Change:	**Updated denominator exclusion:** Added an exclusion to remove patients with a pre-operative visual acuity of better than 20/40.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to revise this measure to include a denominator exclusion to account for patients with a pre-operative visual acuity better than 20/40, as these patients would not be expected to show an improvement in visual acuity following surgical intervention. We believe these patients should be excluded based upon expected visual acuity outcomes. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.55. Follow-up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576
Quality #:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication/Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**Updated denominator:** Added self-harm as a denominator eligible diagnosis. **The measure description is revised to read:** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose the denominator be expanded to include patients diagnosed with self-harm. We agree that this patient population is relevant to this measure and follow-up after hospitalization for patients with a self-harm diagnosis is directly applicable to patient safety.

D.56. HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation

Category	Description
NQF # / eCQM NQF #:	2474
Quality #:	392
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older
Substantive Change:	**The measure title is revised from HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation to read:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.

D.57. HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	393
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**The measure title is revised from HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision to read:** Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update the title to align with the measure steward changing from The Heart Rhythm Society to American College of Cardiology Foundation.

D.58. Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	1407
Quality #:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/ Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.
Substantive Change:	**Updated denominator exclusions:** Added exclusion for encephalopathy due to Tdap vaccine. **Updated numerator to specify compliant serogroups:** Serogroups A, C, W, Y
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose the denominator exclusion be expanded to include encephalopathy as an eligible reason to exclude the patient from the Tdap vaccine clinical action. Both Adacel® and Boostrix® list progressive or unstable neurologic conditions, which would include encephalopathy, as reasons to defer their administration. The numerator was updated to specify the required serogroup. According to the Centers for Disease Control, all 11 to 12 year olds should be vaccinated with a meningococcal conjugate vaccine (Serogroups A, C, W, Y), with a booster dose given at 16 years old. All teens may also be vaccinated with a serogroup B meningococcal vaccine, preferably at 16 through 18 years old. This measure is assessing a younger patient population. We agree with adding specificity to the numerator to align with the current guidelines.

D.59. Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	405
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion ≤ 1.0 cm.
Substantive Change:	**Updated measure assessment:** The measure analytic is being updated and will no longer be inverse. **The measure description is revised to read:** Percentage of final reports for abdominal imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow□up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion ≤ 1.0 cm • Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **The denominator is revised to read:** All final reports for imaging studies for patients aged 18 years and older with one or more of the following incidentally noted: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion ≤ 1.0 cm • Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated denominator note: For the MIPS CQMs Specifications collection type:** Updated to include changes in the denominator and to include: *Other "simple-appearing criteria": • Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated denominator: For the MIPS CQMs Specifications collection type:** Updated criteria: Incidental finding: Cystic renal lesion that is simple appearing* (Bosniak I or II), or Adrenal lesion ≤ 1.0 cm or Adrenal lesion >1.0 cm but ≤ 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** Updated to include changes in the denominator and to include: *Other "simple-appearing criteria": • Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) Radiologists may choose not to include in the radiology report benign-appearing renal cysts (Bosniak I or II or equivalent*) or cystic lesions that are too small to characterize (TSTC) but likely benign (a lesion is too small to characterize (TSTC) when the lesion size is less than twice reconstructed slice thickness (ACR, 2017). **Updated numerator instructions:** Removed inverse measure instructions. Added: A short note can be made in the final report, such as: "No follow-up imaging is recommended as incidental lesions are likely benign " or "No follow-up imaging is recommended per consensus recommendations based on imaging criteria. Further lab evaluation could be pursued based on clinical findings" **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type:** Updated to reflect the changes to what is considered an incidental lesion.

Category	Description
	The numerator is revised to read: Final reports for imaging studies that include a description of incidental cystic renal lesion or adrenal lesion stating follow-up imaging is not recommended. **Updated numerator options:** Updated to reflect changes to the analytics of the measure and what is considered an incidental lesion. **Updated denominator exception:** Updated to read: Documentation of medical reason(s) that follow-up imaging is indicated (e.g., patient has lymphadenopathy, signs of metastasis or an active diagnosis or history of cancer, and other medical reason(s).
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update all aspects of this measure based upon the American College of Radiology's Technical Expert Panel (TEP) recommendations in order to bring the measure into alignment with current guidelines. The measure analytic is also being updated so that it is no longer an inverse measure. In addition, liver lesions have been removed from the denominator and the denominator exception has been updated to reflect the intent of the measure. We agree with these changes as they will bring the measure in better alignment with current clinical guidelines. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.60. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **Update description:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT. **Update denominator exclusions:** Removed pregnancy and revised list of antiplatelets applicable to the exclusion.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type. The benchmarking data shows that this measure is meets the extremely topped out definition for the Medicare Part B Claims Measure Specification collection type. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. Additionally, we propose the denominator exclusions be updated to remove pregnancy as an eligible exclusion due to the low count of exclusion instances, and the list of antiplatelets was revised based upon an in depth review by the quality measures committee and measure leads and now aligns more closely with the current clinical workflow. The description was updated to align with the measure language throughout the specification.

D.61. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated denominator exclusions:** Removed thrombocytopenia.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We are proposing, due to the low count of exclusion instances, to remove thrombocytopenia from the list of eligible denominator exclusions.

D.62. Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053
Quality #:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator exclusions**: Updated: (1) Patients 66 and older who are living long term in an institution for more than 90 days during the measurement period. Added: (1) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. (2) Patients 66 years of age and older with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. (3) Dementia Exclusion Medications: Cholinesterase inhibitors: Donepezil, Galantamine, Rivastigimine Miscellaneous central nervous system agents: Memantine
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose and agree with the measure steward that the denominator exclusions be updated because it is unlikely patients with dementia requiring listed medications or advanced illness and frailty need some services and, in some cases, it might even be harmful for patients to receive a particular service when they should prioritize other services. We are also proposing to update the exclusion for living long term in an institution to include the criteria for more than 90 days during the measurement period. We agree with the measure steward as this would ensure the correct patient population is being removed from the eligible population and will lessen the burden to submit data for these MIPS eligible clinicians.

D.63. Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	438
CMS eCQM ID:	CMS347v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**Updated denominator exception:** Added hospice care.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward proposes to add patients receiving hospice care to the eligible denominator exceptions to align with the intent of the measure. We agree with the measure steward that this patient population should be removed as patients in hospice care would not benefit from this clinical service and we believe that by removing this patient population it will reduce the burden of submission for these MIPS eligible clinicians providing care to these patients.

D.64. Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.
Substantive Change:	**Updated denominator:** Removed exclusion for modifiers 52, 53, 73, and 74.
Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We are proposing that the denominator be expanded to include coded colonoscopy procedures that are indicated as incomplete or discontinued with modifiers 52, 53, 73, or 74 as denominator eligible. We agree that these procedures should be included in the denominator as the measure is looking to assess whether a colonoscopy was clinically indicated for the patient. Even if the colonoscopy was indicated as incomplete or discontinued, we would want that instance included in the denominator to determine if there was a valid medical reason for it to be performed.

D.65. Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	440
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**The measure title is revised from Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician to read:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician. **The measure description is revised to read:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC), Squamous Cell Carcinoma (SCC) (including in situ disease), or melanoma in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist. **Updated denominator:** Added melanoma diagnosis codes. **Updated numerator:** Included language to reflect the addition of melanoma to the denominator.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing that the denominator be expanded to include melanoma diagnosis codes. The measure steward believes this will allow for a broader patient population to reflect communication and care coordination of skin cancers, not just non-melanoma skin cancer. The measure title, description, denominator, and numerator language is being updated to align with the inclusion of a melanoma diagnosis.

D.66. Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	441
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated
Substantive Change:	**Updated denominator exceptions:** Added Procedure-Related BP's not taken during an outpatient visit. Examples of Procedure-related BP Locations: Same Day Surgery, Ambulatory Service Center, G.I. Lab, Dialysis, Infusion Center, Chemotherapy.
Steward:	Wisconsin Collaborative for Healthcare Quality (WCHQ)
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing and agree with the WCHQ Measurement Advisory Committee that procedure-related blood pressures should be excluded from this measure. We agree with the inclusion of the denominator exception as procedure-related blood pressures can be artificially elevated. This change also aligns with other blood pressure related measure exclusions.

D.67. Appropriate Workup Prior to Endometrial Ablation

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	448
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of women, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results documented before undergoing an endometrial ablation.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation. **Updated denominator:** Replace the word "women" with "patients". **Updated numerator:** Replace the word "women" with "patients".
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the measure description to read "percentage of patients" in order to be gender inclusive. This change will also be reflected throughout the measure for consistency.

D.68. Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Category	Description
NQF # / eCQM NQF #:	1858
Quality #:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.
Substantive Change:	**Updated denominator definition:** Use the 2018 ASCO/CAP guideline definitions to determine HER2 status- HER2 Positive: • If result is IHC 3+ based on circumferential membrane staining that is complete, intense and in >10% of the invasive tumor cells • If result is ISH positive based on: • Single-probe average HER2 copy number ≥= 6. 0 signals/cell • Dual-probe HER2/CEP17 ratio ≥= 2. 0 with an average HER2 copy number ≥= 4. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number = 6. 0 signals/cell HER2 Equivocal: • If result is IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells • If result is ISH equivocal based on: • Single-probe ISH average HER2 copy number ≥= 4. 0 and < 6. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number ≥= 4. 0 and < 6. 0 signals/cell HER2 Negative: • If result is IHC 1+ based on incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells • If result is IHC 0 based on no staining observed or membrane staining that is incomplete and is faint/barely perceptible and ≤= 10% of the invasive tumor cells • ISH negative based on: • Single-probe average HER2 copy number < 4. 0 signals/cell • Dual-probe HER2/CEP17 ratio < 2. 0 with an average HER2 copy number < 4. 0 signals/cell HER2 Indeterminate: Report HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include: • Inadequate specimen handling • Artifacts (crush or edge artifacts) that make interpretation difficult • Analytic testing failure.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the denominator definition so that it aligns with the 2018 ASCO/CAP guidelines.

D.69. Average Change in Back Pain Following Lumbar Discectomy / Laminotomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to three months postoperative) in back pain for patients 18 years of age or older who had a lumbar discectomy /laminotomy procedure.
Substantive Change:	**The measure title is revised from Average Change in Back Pain Following Lumbar Discectomy / Laminotomy to read:** Back Pain After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. Removed diagnosis of disc herniation. **Updated denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op pain assessment is greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at 3 months postoperatively (6 to 20 weeks). **Updated definitions:** Added: (1) Back Pain Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure who rates their back pain as less than or equal to 3.0. (2) Back Pain Target #2 - A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9943 is submitted. • VAS Pain Scale is not administered postoperatively at three months (6 to 20 weeks) • Back pain is measured using a different patient reported tool or via telephone screening • Postoperative VAS Pain Scale is administered less than six weeks or more than 20 weeks (3 month window) • Postoperative VAS value is greater than 3.0 and no valid preoperative to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward chose the targets based on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.70. Average Change in Back Pain Following Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to one year postoperative) in back pain for patients 18 years of age or older who had a lumbar fusion procedure.
Substantive Change:	**The measure title is revised from Average Change in Back Pain Following Lumbar Fusion to read:** Back Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being back pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months). **Updated definitions:** Added: (1) Back Pain Target #1 – A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their back pain as less than or equal to 3.0. (2) Back Pain Target #2 – A patient who does not meet Back Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note;** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9946 is submitted. • VAS Pain Scale is not administered postoperatively at one year (9 to 15 months) • Back pain is measured using a different patient reported tool or via telephone screening • Postop VAS Pain Scale is administered less than nine months or more than 15 months (1 year window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward base the target on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is ≤2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.71. Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to three months postoperative) in leg pain for patients 18 years of age or older who had a lumbar discectomy/laminotomy procedure.
Substantive Change:	**The measure title is revised from Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy to read:** Leg Pain After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added the following discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. Removed diagnosis of disc herniation. **Updated denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR a change of 5.0 points or greater on the VAS Pain scale at 3 months postoperatively (6 to 20 weeks). **Updated definitions:** Added: (1) Leg Pain Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure who rates their leg pain as less than or equal to 3.0. (2) Leg Pain Target #2 - A patient who does not meet Leg Pain Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 5.0 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing the chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met G9949 is submitted. • VAS Pain Scale is not administered postoperatively at three months (6 to 20 weeks) • Leg pain is measured using a different patient reported tool or via telephone screening • Postoperative VAS Pain Scale is administered less than six weeks or more than 20 weeks (3 month window) • Postoperative VAS value is greater than 3.0 and no valid preop to measure change • Preoperative VAS Pain Scale (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of change (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0.We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.72. Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	462
CMS eCQM ID:	CMS645v3
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater (indicated by HCPCS code) and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**The measure description is revised to read:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description to align with the removal of the custom HCPCS, J code J1950, which previously denoted the practitioner's intent of androgen deprivation therapy (ADT) for a period of 12 months or greater. The intent of the measure remains intact, but no longer requires the HCPCS to identify the intended patient population.

D.73. Average Change in Functional Status Following Lumbar Fusion Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients 18 years of age and older who had a lumbar fusion procedure.
Substantive Change:	**The measure title is revised from Average Change in Functional Status Following Lumbar Fusion Surgery to read:** Functional Status After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 22, need a pre and post-op assessment to hit the change target of 30 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI) at one year postoperatively (9 to 15 months). **Added numerator definition:** Functional Status Target #1 - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the change is greater than or equal to 30 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change • Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure.) NQF endorsement removed until the measure can be evaluated with the new analytics.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target on a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16 (10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.74. Average Change in Functional Status Following Total Knee Replacement Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oxford Knee Score (OKS) for patients age 18 and older who had a primary total knee replacement
Substantive Change:	**The measure title is revised to read:** Functional Status After Primary Total Knee Replacement. **The measure description is revised:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance patients need a post-op OKS assessment. The measure will now be target-based with performance met being functional status is greater than or equal to 37 on the Oxford Knee Score (OKS) at one year postoperatively (9 to 15 months). Patients who are missing an assessment will be considered numerator non-compliant. **Added numerator definition:** OKS Target - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status score as greater than or equal to 37. **Updated numerator note:** The following situations are those in which the numerator targets cannot be reached and Performance Not Met (M1046) is submitted: • Oxford Knee Score (OKS) is not administered postoperatively at one year (9 to 15 Months) • Functional status is measured using a different patient-reported functional status tool or Oxford Knee Score (OKS) version • Postoperative Oxford Knee Score (OKS) is administered less than 9 Months or greater than 15 Months • Postoperative Oxford Knee Score (OKS) score is less than 37 NQF endorsement removed until the measure can be evaluated with the new analytics.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed that this measure assessment will be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward derived the target from a study "Patient acceptable symptom states after total hip or knee replacement at mid-term follow-up" [Kuerentjes JC, Van Tol FR Bone Joint Res 2014; 3:7–13]. Receiver operating characteristic (ROC) curves identified a PASS threshold of 42 for the OHS after THR and 37 for the OKS after TKR. THR patients with an OHS greater than or equal to 42 and TKR patients with an OKS greater than or equal to 37 had a higher NRS for satisfaction and a greater likelihood of being willing to undergo surgery again. The Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op OKS to determine an equivalent OKS threshold. OKS score greater than or equal to 37 indicates the achievement of an acceptable symptom state and correlates with a higher numeric rating scale for satisfaction [ROC curves PASS threshold of 37 with sensitivity of 76.3% and specificity of 76.5%]. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.75. Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to postoperative) in functional status using the Oswestry Disability Index (ODI version 2.1a) for patients age 18 and older who had lumbar discectomy/laminotomy procedure
Substantive Change:	**The measure title is revised from Average Change in Functional Status Following Lumbar Discectomy/Laminotomy Surgery to read:** Functional Status After Lumbar Discectomy/Laminectomy. **The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated denominator:** Added the following discectomy/ laminectomy CPT procedure codes: 63005, 63012, 63017, 63030, 63042 and 63047. **Update denominator exclusions:** Added spine related cancer, acute fracture or infection, neuromuscular, idiopathic or congenital scoliosis. Removed diagnosis of disc herniation. **Updated numerator:** For numerator compliance patients need either a post-op functional assessment (to meet the target portion) or if post-op greater than 22, need a pre and post-op assessment to hit the change target of 30 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being functional status is less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI) at 3 months postoperatively (6 to 20 weeks). **Added numerator definition:** Functional Status Target #1 - A patient who is assessed postoperatively at three months (6 to 20 weeks) after the procedure rates their functional status as less than or equal to 22. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the change is greater than or equal to 30 points. **Updated numerator note:** It is recommended that both a preoperative and postoperative be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1049 is submitted. • ODI is not administered postoperatively at three months (6 to 20 weeks) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 6 weeks or greater than 20 weeks (3 month window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure change Preoperative ODI (to measure change) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure)
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome

Category	Description
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward derived the target from a study Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine-a Spine Tango registry-based study. vanHooff, ML et al Spine J. 2016 Oct;16(10):1221-1230. Patient Acceptable Symptom State (PASS), the highest level of symptom beyond which patients consider themselves well. PASS was compared to post-op ODI to determine an equivalent ODI threshold. ODI score less than or equal to 22 indicates the achievement of an acceptable symptom state and can be used as a criterion for treatment success. [AUC]: 0.89 [sensitivity: 78.3%, specificity: 82.1%] for 1 year follow-up]. The OR benchmark of change (30) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 22. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. The measure steward's measure development workgroup reached a consensus to expand the denominator to more broadly include all patients undergoing discectomy/laminectomy procedures by removing the diagnosis of disc herniation and adding procedure codes. As a part of this decision, it was decided to add a denominator exclusion as the measure steward believes this will help to create a more heterogeneous population. We agree with the expansion of the denominator to capture all patients undergoing discectomy/laminectomy procedures. Additionally, the definitions and the numerator note are proposed to be updated to align with the other changes and to add clarity. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.76. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	472
CMS eCQM ID:	CMS249v2
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.

Category	Description
Substantive Change:	**Updated guidance:** There are two ways that a patient can be excluded from the measure: 1. The patient has a specific number of "combination" risk factors (the number of risk factors varies by age). 2. The patient has one or more of the "independent" risk factors, including a 10-year probability of major osteoporotic fracture of 8.4 percent or higher as determined by the FRAX. Denominator exclusions statement: Exclude patients with a combination of risk factors (as determined by age) or one of the independent risk factors Ages: 50-54 (>=4 combination risk factors) or 1 independent risk factor Ages: 55-59 (>=3 combination risk factors) or 1 independent risk factor Ages: 60-64 (>=2 combination risk factors) or 1 independent risk factor COMBINATION RISK FACTORS [The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period]: The following risk factors may occur any time in the patient's history but must be active during the measurement period: White (race) BMI <= 20 kg/m2 (must be the first BMI of the measurement period) Smoker (current during the measurement period) Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) The following risk factor may occur any time in the patient's history and must not start during the measurement period: Osteopenia The following risk factors may occur at any time in the patient's history or during the measurement period: Rheumatoid arthritis Hyperthyroidism Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic liver disease Chronic malnutrition The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period: Documentation of history of hip fracture in parent Osteoporotic fracture Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] INDEPENDENT RISK FACTORS (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur at any time in the patient's history and must not start during the measurement period: Osteoporosis The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: Gastric bypass FRAX[R] ten-year probability of all major osteoporosis related fracture >= 8.4 percent Aromatase inhibitors The following risk factors may occur at any time in the patient's history or during the measurement period: Type I Diabetes End stage renal disease Osteogenesis imperfecta Ankylosing spondylitis Psoriatic arthritis Ehlers-Danlos syndrome Cushing's syndrome Hyperparathyroidism Marfan syndrome Lupus **Updated denominator exclusions:** Changed FRAX[R] ten-year probability of all major osteoporosis related fracture result from 9.3% to 8.4%.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process

Category	Description
Rationale:	We are proposing that the denominator exclusion for the Fracture Risk Assessment Tool FRAX® ten-year probability of all major osteoporosis related fracture result be changed from 9.3% to 8.4% to align with the US Preventive Services Task Force (USPSTF) recommendations. We agree with this change as it keeps the measure in alignment with the current clinical guidelines. The guidance is being updated for better alignment with the measure and to align with the updated denominator exclusion.

D.77. Average Change in Leg Pain Following Lumbar Fusion Surgery

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The average change (preoperative to one year postoperative) in leg pain for patients 18 years of age or older who had a lumbar fusion procedure
Substantive Change:	**The measure title is revised from Average Change in Leg Pain Following Lumbar Fusion Surgery to read:** Leg Pain After Lumbar Fusion. **The measure description is revised to read:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. **Updated measure assessment:** Changed measure assessment from continuous variable to a proportional measure. **Updated numerator:** For numerator compliance Patients need either a post-op pain assessment (to meet the target portion) or if post-op greater than 3.0, need a pre and post-op assessment to hit the change target of 5.0 points. Patients who are missing an assessment will be considered numerator non-compliant. The measure will now be target-based with performance met being leg pain is less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at one year postoperatively (9 to 15 months).
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We are proposing that this measure assessment be updated to a target-based measure and will no longer look at the average change. Multiple aspects of the measure are being updated to reflect this change, including requiring all eligible patients undergoing the procedure to be assessed for numerator compliance. The measure steward based the target score on a 2016 study in the Spine Journal Fetke, TF et al "What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?" This study compared the Core Outcomes Measures Index (COMI) and symptom well-being questions to two 0 to 10 graphic ratings scales for back and leg pain. Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For disc herniation, this is less than or equal to 2, and for other degenerative pathologies it is less than or equal to 3. The OR benchmark of improvement (5.0) derived from MNCM data (3 years); the average change in points of patients that did achieve the target of less than or equal to 3.0. We agree with this change as it allows for benchmarking and does not allow denominator self-selection which could skew the results, as patients who do not complete the required assessments will now be considered numerator non-compliant. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

D.78. HIV Screening

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	475
CMS eCQM ID:	CMS349v2
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 15-65 years of age who have been tested for HIV within that age range.
Substantive Change:	**The measure description is revised to read:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV. **The numerator is revised to read:** Patients with documentation of an HIV test performed on or after their 15th birthday and before their 66th birthday.
Steward:	Centers for Disease Control and Prevention
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the measure description to better align the measure specification. We agree with this update as it clarifies the intent of the measure. We propose that the numerator be revised to add clarity and to align the wording with logic used. Neither the intent of the measure nor the numerator action will be changed.

TABLE Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table DD as follows: NQF # / eCQM NQF #.

DD.1. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / ECQM NQF #:	0028 / 0028e
Quality #:	226
CMS eCQM ID:	CMS138v8
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**Updated numerator guidance: for the 2019 performance period: For the CMS Web Interface Measure Specification collection type:** Removed "and the cessation intervention must occur during or after the most recent tobacco user status is documented" language from the guidance.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the numerator guidance in the CMS Web Interface Measure Specifications collection type for the 2019 performance period to remove the guidance given regarding the timing of the tobacco cessation intervention as this does not align with the intent of the measure. The refinements are in alignment with the clinical guidelines and will decrease burden for eligible clinicians performing tobacco screening and tobacco cessation intervention. The timing refinement proposed will maintain the balance of clinical guideline and measure alignment and support our effort to reduce burden for measure submission. Additionally, this timing refinement allows the clinician to create personalized, patient-centered care while still maintaining the clinical integrity of the measure and clinical guidelines. To the extent this proposed change constitutes a change in methodology after the start of the 2019 MIPS performance period, we believe that consistent with section 1871(E)(1)(A)(ii) of the Social Security Act, it would be contrary to the public interest not to modify the measure because the current guidance is inconsistent with the intent of the CMS Web Interface version of this measure and unduly burdensome for clinicians. The proposal is to update the CMS Web Interface Measure Specifications collection type numerator guidance previously stated in the current posted 2019 measure specification for PREV-10 (NQF 0028): Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, available at https://qpp.cms.gov/about/resource-library, in response to extensive stakeholder feedback regarding the timeframe during which the tobacco cessation intervention must occur. Specifically, stakeholders expressed concern that this additional language would not be comparable to the historic benchmark as it changed how the quality action of tobacco cessation intervention was abstracted in terms of numerator compliance. Additionally, stakeholders voiced concern regarding how this change would fit into the current clinical workflow as patients are asked about tobacco use on most if not all encounters, but clinicians do not feel it is necessary to provide tobacco cessation intervention at all encounters especially if it was already completed earlier in the year. Based on this feedback and our review, we have determined that the previously stated guidance is inconsistent with the intent of the CMS Web Interface Measure Specifications collection type version of this measure and unduly burdensome for clinicians. In response to our determination and stakeholder feedback, we are proposing to update the CMS Web Interface Measure Specifications collection type numerator guidance to clarify that screening for tobacco use and tobacco cessation intervention do not have to occur on the same encounter, but must occur during the 24-month look-back period. We agree this proposal will maintain clinical intent, provide clarity, reduce clinician burden, and allow for personalized care.

Appendix 2: Improvement Activities

NOTE: In this proposed rule, for the CY 2020 performance period and future years, we are proposing to: (1) add two new improvement activities; (2) modify seven existing improvement activities; and (3) remove 15 improvement activities from the Inventory. These are discussed in greater detail below.

Table A: Proposed New Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_BE_XX**
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Drug Cost Transparency
Proposed Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).[1])
Proposed Weighting:	High
Rationale:	The costs of prescription drugs is a driving cost of overall health care spending in the United States and of out-of-pocket health care expenses for patients. As we consider broader efforts to increase transparency for patients, payers, provider organizations, and clinicians, as well as begin to drive down drug prices, this activity serves as a mechanism for drug price transparency at the clinician-patient level and may protect patients from unforeseen costs. By discussing drug pricing with patients, clinicians may better prescribe medications patients can afford, which could have the effect of increasing patient medication compliance and adherence. Thus, we believe this proposed activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition which has been codified at § 414.1305. This activity is weighted as high due to difficulties clinicians may have in identifying drug costs and out-of-pocket costs of drugs for individual patients as costs and reimbursement amounts vary by drug and payer, as well as challenges with identifying the appropriateness of patient assistance programs.[2 3] As stated previously, we have given certain improvement activities high-weighting due to the intensity of the activity (81 FR 77194). To summarize, we believe that an activity that requires significant investment of time and resources should be high-weighted.
Proposed Activity ID:	**IA_CC_XX**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes.
Proposed Activity	To receive credit for this improvement activity, a MIPS eligible clinician must attest

Description:	that they reported MACRA patient relationship codes (PRC) using the applicable HCPCS modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period. Reporting the PRC modifiers enables the identification of a clinician's relationship with, and responsibility for, a patient at the time of furnishing an item or service. See the CY 2018 PFS final rule (82 FR 53232 through 53234) for more details on these codes.
Proposed Weighting:	High
Rationale:	The patient relationship categories and codes define and distinguish the relationship and responsibilities of a clinician with a patient at the point of furnishing an item or service. These codes provide insight into clinician interactions with patients and identify the clinician's relationship to and responsibility for the patient at the time of furnishing an item or service. These codes were developed, as required under section 1848(r)(3) of the Act, to facilitate the attribution of patients and episodes to one or more clinicians. Beginning in 2018, clinicians started voluntarily reporting the patient relationship codes using the applicable HCPCS modifiers (82 FR 53232 through 53234). To properly report the code modifiers, clinicians must add one of the modifiers to each claim line. We propose that, for the CY 2020 performance period and beyond, clinicians who choose to report the modifiers on 50 percent or more of their Medicare claims for a minimum of a continuous 90-day period within the performance period would earn one (1) high-weighted improvement activity. We believe reporting these modifiers would provide the minimum sample of data necessary to access the modifiers' ability to capture the clinician's relationship with the patient and whether the clinician is appropriately reporting the modifiers. This improvement activity is weighted as high due to the intensity of the activity. We believe reporting the modifiers to each claim line for 50 percent or more of Medicare claims continuously for 90 days requires significant investment of time and resources and should be weighted high. For the initial and current period of voluntary reporting the PRC modifiers, where clinicians gain familiarity, data collected will be used to provide aggregate feedback on the performance of clinicians in using the codes within different clinical scenarios and specialties. Data collected from this activity will be used to test the reliability and validity of the modifiers in measuring the clinician's relationship to and responsibility for the Medicare patient before we consider whether to propose in future rulemaking to require the reporting of the PRC modifiers on claims. In the event that we do decide to require such reporting, we would likely propose to remove this improvement activity from MIPS.

1/ See the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, Final Rule, 84 FR 23832, 23883 (May 23, 2019).

2/Allan GM, Lexchin J, Wiebe N. *Physician awareness of drug cost: a systematic review*. PLoS Med. 2007 Sep;4(9):e283. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/17896856

3/ Arora V, Moriates C, Shah N. *The challenge of understanding health care costs and charges*. AMA Journal of Ethics. 2015;17(11): 1046. doi: 10.1001/journalofethics.2015.17.11.stas1-1511.

TABLE B: Proposed Changes to Previously Adopted Improvement Activities for the MIPS CY 2020 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_28**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Completion of an Accredited Safety or Quality Improvement Program
Current Activity Description:	Completion of an accredited performance improvement continuing medical education program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain)" as an example of an accredited continuing medical education (CME) program that could meet this improvement activity. Due to the importance of safe prescribing to prevent opioid misuse and opioid use disorder, CME programs related to opioid analgesic REMS may be especially useful to MIPS eligible clinicians in their attempts to prevent opioid misuse among their patients and combat the opioid epidemic.
Proposed Revised Activity Description:	Completion of an accredited performance improvement continuing medical education (CME) program that addresses performance or quality improvement according to the following criteria: • The activity must address a quality or safety gap that is supported by a needs assessment or problem analysis, or must support the completion of such a needs assessment as part of the activity; • The activity must have specific, measurable aim(s) for improvement; • The activity must include interventions intended to result in improvement; • The activity must include data collection and analysis of performance data to assess the impact of the interventions; and • The accredited program must define meaningful clinician participation in their activity, describe the mechanism for identifying clinicians who meet the requirements, and provide participant completion information. An example of an activity that could satisfy this improvement activity is completion of an accredited continuing medical education program related to opioid analgesic risk and evaluation strategy (REMS) to address pain control (that is, acute and chronic pain).
Current Improvement Activity	
Current Activity ID:	**IA_PM_2**
Current Subcategory:	Population Management
Current Activity Title:	Anticoagulant Management Improvements
Current Activity Description:	Individual MIPS eligible clinicians and groups who prescribe oral Vitamin K antagonist therapy (warfarin) must attest that, for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, their ambulatory care patients receiving warfarin are being managed by one or more of the following improvement activities: • Patients are being managed by an anticoagulant management service, that involves

	systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up; and patient communication of results and dosing decisions; and/or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Current Weighting:	High
Proposed Change and Rationale:	Addition of "anti-coagulation medications (oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors)"; and "Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program)." This language was consolidated from IA_PM_1, proposed for removal in Table C. We believe IA_PM_1 is duplicative in content to, but less robust than IA_PM_2, with overall fewer examples of actions that can be undertaken to satisfy the intent of the improvement activity. However, IA_PM_1 contained more detail about the type of anti-coagulation medication that could be prescribed to satisfy this activity and an additional example of an action that can be undertaken to satisfy the intent of IA_PM_2, participation in systematic anticoagulation program; so these elements of IA_PM_IA were added to IA_PM_2. Removal of ", for 60 percent of practice patients in the transition year … in Quality Payment Program Year 2 and future years". These time references to transition year and Quality Payment Program Year 2 are now irrelevant because they are in the past. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposal to remove IA_PM_1 as discussed in Table C.
Proposed Revised Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM)

	program.
Current Improvement Activity	
Current Activity ID:	**IA_EPA_4**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Current Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services (for example, investment of on-site diabetes educator).
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "or improve care coordination". We are proposing to consolidate this language from activity IA_CC_3, which is being proposed for removal in Table C. IA_CC_3 is duplicative to IA_EPA_4 in content related to Quality Innovation Network-Quality Improvement Organization technical assistance, but referred to improving care coordination. We believe the Quality Innovation Network-Quality Improvement Organization technical assistance can support both access to services and care coordination[1] and, furthermore, that care coordination and access to services are inherently related and can logically be combined into one improvement activity. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposal to remove IA_CC_3 as discussed in Table C.
Proposed Revised Activity Description:	As a result of Quality Innovation Network-Quality Improvement Organization technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_19**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of formal quality improvement methods, practice changes, or other practice improvement processes
Current Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following such as: • Multi-Source Feedback; • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties; • Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of "Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program". This language was added to consolidate it from IA_PSPA_14 proposed for removal in Table B. We believe IA_PSPA_14 is duplicative in content, but less robust than IA_PSPA_19 related to adopting a model for quality improvement. However, IA_PSPA_14 contains a unique relevant example that we wish to preserve under IA_PSPA_19. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposal to remove IA_PSPA_14 as discussed in Table C.
Proposed Revised Activity Description:	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following, such as: • Participation in multisource feedback; [2] • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties;

	• Engage all staff in identifying and testing practices changes; • Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families, including activities in which clinicians act upon patient experience data; • Participation in Bridges to Excellence;[3] • Participation in American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.[4]
Current Improvement Activity	
Current Activity ID:	**IA_BE_7**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Activity Description:	Participation in a QCDR, that promotes use of patient engagement tools.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing the addition of activity description language from four other improvement activities related to participation in QCDR; IA_BE_11. Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan; IA_BE_2 Use of QCDR to support clinical decision making; IA_BE_9 Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement; and IA_BE_10 Participation in a QCDR, that promotes implementation of patient self-action plans. The activity description will include the current (IA_BE_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"…, including: • "The use of processes and tools that engage patients for adherence to treatment plans" (from IA_BE_11); • "Activities that promote implementation of shared clinical decision making capabilities" (from IA_BE_2); • "Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" (from IA_BE_9); • "Activities that promote implementation of patient self-action plans" (from IA_BE_10). This language was added to consolidate activity description language from improvement activities being proposed for removal in Table C (IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10). The activities we propose to remove are duplicative to IA_BE_7. We are also proposing to remove the language "use of…tools" to better capture the content of the consolidated improvement activity regarding promoting patient engagement more broadly. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposals to remove IA_BE_11, IA_BE_2, IA_BE_9, and IA_BE_10 as discussed in Table C.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR), that promotes patient engagement, including: • Use of processes and tools that engage patients for adherence to treatment plans; • Implementation of patient self-action plans; • Implementation of shared clinical decision making capabilities; or • Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Improvement Activity	

Current Activity ID:	**IA_PSPA_7**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of QCDR data for ongoing practice assessment and improvements
Current Activity Description:	Use of QCDR data, for ongoing practice assessment and improvements in patient safety.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing the addition of activity description language from four other improvement activities related to participation in QCDR; IA_CC_6 Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination; IA_AHE_4 Leveraging a QCDR for use of standard questionnaires; IA_AHE_2 Leveraging a QCDR to standardize processes for screening; and IA_PM_10 Use of QCDR data for quality improvement such as comparative analysis reports across patient populations. The activity description will include the current (IA_PSPA_7) activity description with the addition of "Participation in a Qualified Clinical Data Registry and"… including: • "Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups)" (from IA_CC_6); • "Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment)" (from IA_AHE_4); • "Use of standardized processes for screening for social determinants of health such as food security, employment and housing" from (from IA_AHE_2); • "Use of supporting QCDR modules that can be incorporated into the certified EHR technology" (This language adapted from IA_AHE_2 and updated to replace "tools" with "QCDR modules" to add additional specificity to the action that can be taken in the QCDR to promote ongoing practice assessment and patient safety.); or • "Use of QCDR data for quality improvement (such as) comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" (from IA_PM_10). This language was added to consolidate improvement activity description language from activities (IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10) proposed for removal in Table C. The activities we propose to remove are duplicative to IA_PSPA_7. We note that this proposed change is made in conjunction with and is contingent upon finalization of our proposals to remove IA_CC_6, IA_AHE_4, IA_AHE_2, and IA_PM_10 as discussed in Table C.
Proposed Revised Activity Description:	Participation in a Qualified Clinical Data Registry (QCDR) and use of QCDR data for ongoing practice assessment and improvements in patient safety, including: • Performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups); • Use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire[5], MD Anderson Symptom Inventory[6], and/or SF-12/VR-12 functional health status assessment[7]; • Use of standardized processes for screening for social determinants of health such as food security, employment, and housing; • Use of supporting QCDR modules that can be incorporated into the certified EHR technology; or • Use of QCDR data for quality improvement such as comparative analysis across

	specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_10**
Current Subcategory:	Behavioral and Mental Health
Current Activity Title:	Completion of Collaborative Care Management Training Program
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI), available to the public, in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Current Weighting:	Medium
Proposed Change and Rationale:	We are proposing to remove reference of the CMS Transforming Clinical Practice Initiative (TCPI) in the activity description. This initiative is ending on September 28, 2019,[9] and therefore, will no longer be applicable to this improvement activity description after said date. The example training program referenced, the APA Collaborative Care Model, continues to be available to the public. The revised activity description only proposes to remove reference to TCPI.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychiatric Association (APA) Collaborative Care Model training program available to the public[8], in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.

1/ Quality Improvement Organizations. About QIN-QIO. Available at https://qioprogram.org/about/why-cms-has-qios.

2/ Multisource feedback (MSF), or 360-degree employee evaluation, is a questionnaire-based assessment method in which rates are evaluated by peers, patients, and coworkers on key performance behaviors. More information available at https://www.ncbi.nlm.nih.gov/pubmed/12739254.

3/ Bridges to Excellence program. More information available at http://www.bridgestoexcellence.org/.

4/ American Board of Medical Specialties Portfolio Program. More information available at https://mocportfolioprogram.org/about-us/.

5/ The Seattle Angina Questionnaire is a self-assessed health-related quality of life instrument for coronary artery disease. See: Spertus JA et al. *Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease.* J Am Coll Cardiol. 1995 Feb;25(2):333-41. Available at https://www.ncbi.nlm.nih.gov/pubmed/7829785.

6/ The MD Anderson Symptom Inventory (MDASI) is a multi-symptom patient-reported outcome (PRO) measure for clinical and research use. Available at https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/md-anderson-symptom-inventory.html.

7/ The Optum SF Health Surveys are patient-reported outcome (PRO) surveys across eight health domains. Available at https://www.optum.com/solutions/life-sciences/answer-research/patient-insights/sf-health-surveys.html?s=PPC&pstc=optum:ppc:LS_4.1_2018:g:ls:Frm:18wd1fk01rr23&ppcid=sf12&adid=323753202402&adgroupid=52618954298&campaignid=1036340767&o=optum:ppc:LS_4.1_2018:frm:ls:Frm:18wd1fk01rr23&gclid=Cj0KCQjwg73kBRDVARIsAF-kEH_sDfonepf7U7tsZzzLcHc15b_DxREHpFu0kNGwu2ANu-33WiGoSBIaAgIdEALw_wcB.

8/ The American Psychiatric Association (APA) Collaborative Care Model has been shown to be an effective and efficient model in delivering integrated care. More information on this model and the training program is available at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/learn.

9/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

TABLE C: Improvement Activities Proposed for Removal for the MIPS CY 2020 MIPS Performance Period and Future Years

In this rule, we are proposing to remove 14 previously finalized improvement activities from the MIPS Program for the MIPS CY 2020 performance period and future years. These improvement activities are discussed in detail below. Improvement activity proposed removal factors are discussed in section III.K.3.c.(3) of this proposed rule.

Current Improvement Activity	
Current Activity ID:	**IA_PM_1**
Current Subcategory:	Population Management
Current Activity Title:	Participation in Systematic Anticoagulation Program
Current Activity Description:	Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program) for 60 percent of practice patients in the transition year and 75 percent of practice patients in Quality Payment Program Year 2 and future years, who receive anti-coagulation medications (warfarin or other coagulation cascade inhibitors).
Current Weighting:	High
Removal Rationale:	We are proposing to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PM_2. We are proposing to consolidate the unique language from IA_PM_1 into IA_PM_2 per the proposed change in Table B. The proposed revised IA_PM_2 adds additional detail from IA_PM_1. We note that this proposed removal is made in conjunction with our proposal to change IA_PM_2 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_CC_3**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of additional activity as a result of TA for improving care coordination
Current Activity Description:	Implementation of at least one additional recommended activity from the Quality Innovation Network-Quality Improvement Organization after technical assistance has been provided related to improving care coordination.
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove IA_CC_3 under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_EPA_4. We are proposing to consolidate the unique language from IA_CC_3 into IA_EPA_4 per the proposed change in Table B. The proposed modified language to IA_EPA_4 adds the outcome of "improve care coordination" from the proposed removed activity to make IA_EPA_4 more robust. We note that this proposed removal is made in conjunction with our proposal to change IA_EPA_4 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_14**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in Quality Improvement Initiatives
Current Activity Description:	Participation in other quality improvement programs such as Bridges to Excellence or American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program.
Current Weighting:	Medium

Removal Rationale:	We are proposing to remove this IA_PSPA_14 under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of the activities included in IA_PSPA_19. We are proposing to consolidate the unique language in IA_PSPA_14 with IA_PSPA_19 per the proposed change in Table B. The proposed modified language to IA_PSPA_19 adds the examples "Bridges to Excellence" and "American Board of Medical Specialties (ABMS) Multi-Specialty Portfolio Program" as additional actions that an eligible clinician or group can take to participate in a quality improvement program. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_19 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_5**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Annual Registration in the Prescription Drug Monitoring Program
Current Activity Description:	Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and groups must participate for a minimum of 6 months.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar in content but less robust than the currently adopted IA_PSPA_6. IA_PSPA_6 requires consultation of and specific thresholds of use for a prescription drug monitoring program instead of simply registering in a prescription drug monitoring program as described in IA_PSPA_5. Because of this, we believe IA_PSPA_6 already captures the essence of IA_PSPA_5 and would directly fall into that improvement activity. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this referenced proposal.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_24**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Initiate CDC Training on Antibiotic Stewardship
Current Activity Description:	Completion of greater than 50 percent of the modules of the Centers for Disease Control and Prevention antibiotic stewardship course. Note: This activity may be selected once every 4 years, to avoid duplicative information given that some of the modules may change on a year by year basis, but over 4 years there would be a reasonable expectation for the set of modules to have undergone substantive change, for the improvement activities performance category score.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is less robust than IA_PSPA_23. IA_PSPA_23 requires completion of all modules of a Centers for Disease Control and Prevention antibiotic stewardship course, instead of 50 percent of modules of a Centers for Disease Control and Prevention antibiotic stewardship course. Because of this, we believe IA_PSPA_23 already captures the essence of IA_PSPA_24 and would directly fall into that improvement activity. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this referenced proposal.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_3**
Current Subcategory:	Behavioral and Mental Health

Current Activity Title:	Unhealthy alcohol use
Current Activity Description:	Unhealthy alcohol use: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including screening and brief counseling (refer to NQF #2152) for patients with co-occurring conditions of behavioral or mental health conditions.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to the currently adopted IA_BMH_9. We believe IA_BMH_9 is more robust because it requires a threshold of patients for which this unhealthy alcohol use screening must be completed, whereas IA_BMH_3 simply requires engagement, screening and counseling without such a threshold. Because of this, we believe IA_BMH_9 already captures the essence of IA_BMH_3 and would directly fall into that improvement activity. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this referenced proposal.
Current Improvement Activity	
Current Activity ID:	**IA_BE_11**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan
Current Activity Description:	Participation in a QCDR, that promotes use of processes and tools that engage patients for adherence to treatment plan.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 that add "…the use of processes and tools that engage patients for adherence to treatment plan" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_11. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_BE_2**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR to support clinical decision making
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities that promote implementation of shared clinical decision making capabilities.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 that add "activities that promote implementation of shared clinical decision making capabilities" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_2. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_BE_9**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of QCDR patient experience data to inform and advance improvements in

	beneficiary
Current Activity Description:	Use of QCDR patient experience data to inform and advance improvements in beneficiary engagement.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 that add "use of QCDR patient experience data to inform and advance improvements in beneficiary engagement" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_9. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_BE_10**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Participation in a QCDR, that promotes implementation of patient self-action plans.
Current Activity Description:	Participation in a QCDR, that promotes implementation of patient self-action plans.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_BE_7. In Table B, we are proposing changes to IA_BE_7 to add "[activities that] promote implementation of patient self-action plans" to make IA_BE_7 more robust and offer an additional example. Because of this, we believe the proposed changes to IA_BE_7 would capture the essence of IA_BE_10. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_CC_6**
Current Subcategory:	Care Coordination
Current Activity Title:	Use of QCDR to promote standard practices, tools and processes in practice for improvement in care coordination
Current Activity Description:	Participation in a Qualified Clinical Data Registry, demonstrating performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes to IA_PSPA_7 to add "performance of activities that promote use of standard practices, tools and processes for quality improvement (for example, documented preventative screening and vaccinations that can be shared across MIPS eligible clinician or groups);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_CC_6. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_4**

Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR for use of standard questionnaires
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes to IA_PSPA_7 to add "use of standard questionnaires for assessing improvements in health disparities related to functional health status (for example, use of Seattle Angina Questionnaire, MD Anderson Symptom Inventory, and/or SF-12/VR-12 functional health status assessment);" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_AHE_4. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_2**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Leveraging a QCDR to standardize processes for screening
Current Activity Description:	Participation in a QCDR, demonstrating performance of activities for use of standardized processes for screening for social determinants of health such as food security, employment and housing. Use of supporting tools that can be incorporated into the certified EHR technology is also suggested.
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes to IA_PSPA_7 to add "use of standardized processes for screening for social determinants of health such as food security, employment and housing…use of supporting tools that can be incorporated into the certified EHR technology" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_AHE_2. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_PM_10**
Current Subcategory:	Population Management
Current Activity Title:	Use of QCDR data for quality improvement such as comparative analysis reports across patient populations
Current Activity Description:	Participation in a QCDR, clinical data registries, or other registries run by other government agencies such as FDA, or private entities such as a hospital or medical or surgical society. Activity must include use of QCDR data for quality improvement (for example, comparative analysis across specific patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcome).
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 1, improvement activity is "duplicative." We believe it is duplicative, because it is similar to, but only represents a partial component of IA_PSPA_7. In Table B, we are proposing changes

	to IA_PSPA_7 to add "use of QCDR data for quality improvement such as comparative analysis reports across patient populations for adverse outcomes after an outpatient surgical procedure and corrective steps to address adverse outcomes" to make IA_PSPA_7 more robust and offer additional examples. Because of this, we believe the proposed changes to IA_PSPA_7 would capture the essence of IA_PM_10. We note that this proposed removal is made in conjunction with our proposal to change IA_PSPA_7 in Table B, as well as our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of both referenced proposals.
Current Improvement Activity	
Current Activity ID:	**IA_CC_4**
Current Subcategory:	Care Coordination
Current Activity Title:	TCPI Participation
Current Activity Description:	Participation in CMS Transforming Clinical Practice Initiative
Current Weighting:	Medium
Removal Rationale:	We propose to remove this activity under proposed removal factor 7, improvement activity is obsolete. The Transforming Clinical Practice Initiative is ending on September 28, 2019[1] and therefore, clinicians will no longer be able to attest to this improvement activity after that date. We note that this proposed removal is made in conjunction with our proposal to adopt removal factors in section III.K.3.c.(3) of this proposed rule. Therefore, this proposed removal is contingent upon finalization of this proposal.

1/ Transforming Clinical Practice Initiative. Available at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

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